103

NATIONAL CANCER INSTITUTE'S REVISION OF ITS MAMMOGRAPHY GUIDELINES

Y 4.G 74/7:C 16/3

National Cancer Institute's Revisio...

HEARING

BEFORE THE

HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

MARCH 8, 1994

Printed for the use of the Committee on Government Operations

JAN 19 1995

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NATIONAL CANCER INSTITUTE'S REVISION OF ITS MAMMOGRAPHY GUIDELINES

TUESDAY, MARCH 8, 1994

HOUSE OF REPRESENTATIVES,
HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
OF THE COMMITTEE ON GOVERNMENT OPERATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2203, Rayburn House Office Building, Hon. Edolphus Towns (chairman of the subcommittee), presiding.

Present: Representatives Edolphus Towns, Thomas M. Barrett, Steven Schiff, John L. Mica, Rob Portman, and Bernard Sanders.

Also present: Ronald A. Stroman, staff director; Allegra A. Pacheco, professional staff member; Martine M. DiCroce, clerk; amd Martha Morgan, minority professional staff, Committee on Government Operations.

OPENING STATEMENT OF CHAIRMAN TOWNS

Mr. TOWNS. The Subcommittee on Human Resources and Intergovernmental Relations will come to order.

Last December, in an unprecedented move, the National Cancer Institute overruled the recommendations of its advisory board and eliminated its mammography guidelines for women between the ages of 40 and 49. The advisory board, composed of scientific and medical experts, and cancer activists, all appointed by the President of the United States, voted 14 to 1 that NCI should not change its guidelines because the research on mammography is unclear at this time.

With such a momentous decision affecting the lives of thousands of women, NCI's decision should have had solid evidence and research to support this. And yet, NCI's own advisory board, nearly the entire cancer and medical establishment—from the American Cancer Society, the American Medical Association, to the National Medical Association—former NCI employees, scientists, and doctors, all claimed that the evidence NCI relied upon was not strong enough at this point in time to justify revising the mammography guidelines.

Indeed, had NCI utilized a process that took into account all the controversial evidence, it may have reached the same conclusions that its own advisory board and the medical organization hold to this very day: Women in their forties need to continue regular mammography screening.

What NCI has done, is to unravel the last 7 years of intense campaigning and millions of dollars spent on educating women in their forties about the importance of mammography. As you can see from the posters we have set up—each member should have a copy of these posters in their folders—NCI has been sending a very strong message on mammography to women in their forties.

Look at the messages women heard [reads from posters]. "Cancer screening could save 13,500 lives." "Don't wait! The NCI recommends that once you turn 40, have a mammogram every one or two years." "It is far more dangerous to allow breast cancer to go undetected than to be exposed to the very low dose of radiation from mammography."

After all the energy and resources NCI expended over these 7 years, and in the face of heavy opposition and the near unanimous vote by its advisory board, it seems wholly irresponsible of NCI to change course so dramatically at this time.

The change of personnel at NCI in the Early Detection Branch in charge of the guidelines, culminating with the retirement of Dr. Charles Smart as the head of this branch just a few years ago, may shed some light on the reason for the radical retrenchment.

The change in personnel has facilitated academics and M.D.'s with little medical experience with breast cancer patients to set in motion an agenda to impose science over medicine and change the guidelines. And they have done just that.

NCI states that it has evaluated all the legitimate science on this issue consisting of eight randomized clinical trials, and that these trials show that mammography screening has no benefit on women in this age group. This evidence, however, as one NCI employee informed our staff, is simply anecdotal and not to be considered. Only the scientific trials dictate the truth.

NCI's reliance solely on these eight randomized clinical trials to set the mammography guidelines for millions of women in this country remains questionable. Of these eight trials, only 30 percent of the participants were in the 40 to 49 age group. Further, only one trial was conducted on American women, and that was the oldest trial in the group with the oldest technology. Indeed, I fail to understand how NCI can take the unprecedented move based on a science that evaluated Swedish, Canadian, and English population groups lacking the ethnic and minority makeup of American women. How ironic it is that the Swedish Government, despite the evidence from their own trials, mandates that women in their forties receive mammography screening, and our own National Cancer Institute, using studies on foreign women, darts its responsibility for advising American women about the most assured way to detect breast cancer.

I say we cannot make life and death decisions based solely on controversial, randomized clinical trials, when other scientific and medical evidence shows that mammography does benefit women and national cancer and medical organizations and NCI's own advisory board all continue to advise that women in their forties should continue to get mammography screenings. This is not just a matter of pure science, but also of medicine, policy, and the experience of thousands of women in this country.

The elimination of the guidelines will have a severe impact on women. Without the guidelines, women will be discouraged from getting mammography and, that, will lead to many unnecessary deaths from the later detections of breast cancer. The elimination of the guidelines also forms the best pretext for insurance companies not to cover mammograms and allows health care reform to cut costs and not provide mammography coverage for women in this age group. Finally, it causes serious confusion to women who do not know what a randomized clinical trial is and who are not aware of all the other science that shows a benefit to women.

After several months of investigation and interviews with key NCI employees, I believe that the process NCI utilized to revise its guidelines was biased and flawed and, from the start, was designed to eliminate mammography screening guidelines for women between the ages of 40 and 49.

The evidence suggests that a rational and objective evaluation of the evidence did not occur in this situation. The fact that NCI withheld key documents from the subcommittee until the 11th hour adds to the subcommittee's concerns about the impropriety of NCI's actions.

As Chair, I believe that NCI has not fully cooperated with the subcommittee in an open and forthright manner. I remain seriously concerned about this matter and I will not let this go unnoticed. As chairman of this subcommittee, I look forward to getting some answers from NCI and from all of our other witnesses today because this is a very serious subject.

Before we hear from our witnesses, I would like to yield to the ranking member of the subcommittee for any remarks that he might have at this time who has been very involved in this issue from day 1. I now yield to Congressman Schiff from Albuquerque, NM. Congressman Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman.

Very briefly, first, I want to commend you for having this hearing. I want to thank the witnesses who are about to testify, especially our colleagues, Representative Snowe, Representative Schroeder, Representative Slaughter, and former Representative Oakar. Welcome to the subcommittee.

I want to say that several things here are very disturbing to me. First, the more information I see on this, the more witnesses have sent us statements, indicates to me that the National Cancer Institute has gone in the opposite direction of the overwhelming majority of professional, medical opinion on this subject, and that they appear to have not only gone against the weight of medical opinion, which would have continued the previous guidelines that would have encouraged mammography for women between the ages of 40 and 49, but they seem to have rushed to do so.

And it is amazing to me, and something that I hope will be explained during this hearing, that in view of the contrary information, that such apparently swift action was taken.

Second of all, it is more than disturbing, it is frightening the continued implication that, in fact, the decision to change the guidelines to not recommend mammography before the age of 50 was actually dollar-driven and not medically driven, and that the implied purpose was to make anticipated figures, intended to be spent on

medical care, fit the medical requirements, rather than the reverse of the situation, which is to say, "Let us determine the medical requirements and then plan a budget around that."

And it seems to me that whether the implication is for the administration's proposed health care plan or for overall national health care spending targets involving private insurance companies, that's not what's important, and that's not what I'm getting at.

What I think is absolutely frightening is the idea that we might be setting medical standards second, based upon dollar projection first. And I hope that that will not be shown the case during the course of this hearing, but I'm very much afraid that's exactly what's going on here.

Thank you, Mr. Chairman. I yield back.

Mr. TOWNS. Thank you very much, Congressman Schiff.

Before we begin, I would like to have the subcommittee and the audience view a short news clip that I think puts into context the importance of the hearing today.

[Videotape shown.]

Mr. TOWNS. The subcommittee felt that the video would sort of set the tone. We will apply the 5-minute rule. The full text of all written statements will be inserted in the hearing record. I ask for everyone's cooperation.

I'm delighted to have our distinguished colleagues join us today, and also one former colleague, who has been very, very involved in these issues for a long time. We're delighted to have the Congresswoman Pat Schroeder from Colorado, Congresswoman Louise Slaughter from my home State of New York, Congresswoman Olympia Snowe from the State of Maine, and of course former Congresswoman Mary Rose Oakar from the State of Ohio.

We're delighted to have all of you join us today. Why don't we start with you, Congresswoman Schroeder.

STATEMENT OF HON. PAT SCHROEDER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Mrs. SCHROEDER. Well, thank you, Mr. Chairman, and thank you so much for showing the leadership that you have on this. Basically, Olympia and I are here to give support to Congresswoman Slaughter, who's been a great leader on this.

I also want to thank the subcommittee for showing my home TV station and how they have been pursuing this, because in all honesty, the caucus, under Congresswoman Slaughter's leadership, has come up saying, "This is absolute nonsense and we won't stand for this. We want something entirely different in the plan."

I am going to put my statement in the record. I must say, as I watch all of that, I get very frustrated. And as I look at your posters, I get very angry. I mean, are not 13,500 women's lives enough? Please, if they say that that screening could save 13,500 women, that, to me, sounds like enough to do screening between the ages of 40 and 49.

When you listen to the debate about prostate, that's all confused, too. There's nobody that knows exactly what to do about prostate cancer, but isn't it interesting that no one's coming out and putting in hard guidelines and saying, "No, they shouldn't be screened,

they shouldn't do this, they shouldn't do that," but with women, they do. I don't know. I must say, I get very frustrated sometimes. You almost begin to wonder if they think that mammograms are such fun to have that if they cover the screening, every American woman will be down there getting one every other day. It only says to me they haven't had one. These are not exactly pleasant things to do.

And we, in the women's caucus, have worked very hard to try and get women to go get mammograms. I remember just a couple of years ago we were out doing an awareness of trying to get women to go out and get mammograms, and Congresswoman Lloyd was standing next to me and said she didn't think she'd had one in a year. She went home that weekend. She had one. They found a lump and she had immediate surgery. That's how serious it was. But had she not done that, she wouldn't be with us today.

Now, for all the work that we've done trying to prod women to do it, and it's been very difficult—the first time breast cancer was even mentioned on television it was Edith Bunker. People have kept this hidden. They haven't talked about this. And to think that we're finally making that, and then to see NCI roll it all back, saying, "Well, you know, maybe not, and we aren't going to pay for it."

I'm very frustrated. But it fits in exactly with what the caucus has seen with how the Federal Government has treated women's health all across the board. We have all the studies showing they didn't have women in any of the National Institutes of Health's studies, whether it was heart disease or, as Congresswoman Snowe pointed out, they even did one of the breast cancer studies on men, which I think is a little unique.

In fact, they didn't even use female rats over at NIH, which is kind of extreme. And we now find that the Food and Drug Administration doesn't do any gender-specific questions when they get in there. Congresswoman Snowe and I and the caucus are all trying to change that.

But for some reason, they've played very fast and loose with women's health. You almost have this feeling that the Federal Government's position is women may as well go see veterinarians, because we really don't have any hard data or specific evidence or real focus on these diseases, and we're very, very tired of it. And I think this is just one more final insult.

So I am very thrilled to have Mary Rose Oakar here with us, who worked so hard putting mammograms in Medicare. It took time after time after time. We finally got it in in 1990, but she had to go to the floor and threaten to bring down the entire budget if it didn't happen. And here we are again talking about how the health care train will leave the station and women, once again, may not be on it in equal seats.

Well, a lot of us aren't going to support any plan that doesn't treat women equitably, and so the caucus, under Congresswoman Slaughter's leadership, has really aggressively moved out there.

We thank you for giving us this chance and for joining us in protesting this, and I think when the brothers and sisters stand together, maybe we'll finally make some progress. So thank you very much.

[The prepared statement of Mrs. Schroeder follows:]

TESTIMONY OF

REP. PAT SCHROEDER (D-CO)

HOUSE GOVERNMENT OPERATIONS

SUBCOMMITTEE ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS

MARCH 8, 1994

WASHINGTON, D.C.

Mr. Chairman, thank you for allowing me and my colleagues from the Congressional Caucus for Women's Issues to testify before you today. You've been very supportive in caucus efforts to provide equity for women and minorities, and I want to thank you for that.

Mr. Chairman, we've got 46,000 American women expected to die this year of breast cancer, another 182,000 expected to be diagnosed with it, and here women are in the same boat. Once again, the experts don't have enough data, or the right data, to say how effective screening mammograms are for women in their forties. And the tragic part is we don't have much else to offer them, except clinical and self-breast exams. And as we know, those can miss a lot.

If this sounds familiar, it is. It should be nothing new to anyone here that women continue to be an afterthought when it comes to their health care and the research behind it.

A 1990 General Accounting Office report showed women weren't even included in National Institutes of Health-sponsored clinical trials. That prompted the Women's Health Equity Act -- 32 bills sponsored by the caucus to improve research and services for women. And now women and minorities must be included in NIH-sponsored clinical trials.

Then we had the 1992 GAO study that revealed women and minorities were being systematically left out of drug studies by private pharmaceutical companies, as regulated by the Food and Drug Administration. So Congresswoman Olympia Snowe and I developed legislation to correct that.

Of course in 1991, the Office of Technology Assessment found our medicine to be lacking in even basic information on menopause and hormone therapy. And we know little about the effects of taking a given drug during pregnancy, drug interactions with oral contraceptives, and a host of other research issues crucial to women's health. The list goes on and on. And while we wait for someone to take an interest, women needlessly suffer and die.

Now in recent caucus meetings with experts we have found we know little about how best to diagnose and treat the deadly disease of breast cancer. The experts tell us that mammography may not even be the most effective screening device for breast cancer for younger women.

To compound this, women are getting all sorts of confusing messages from the players in health care reform.

The President's plan provides for routine screening mammograms every two years for women over 50, with no cost-sharing. However, women of any age who are determined to be at-risk for breast cancer may receive more frequent screenings, again with no cost-sharing.

But under the Clinton plan, screenings would be covered with co-payments and deductibles at any time only when "medically appropriate." The problem is, no one knows what "medically appropriate" means.

Then we have the American Cancer Society, which calls for screening of women over 40 and for more frequent screening for women over 50.

And now we have the National Cancer Institute, which threw a real wrench into the works recently when it said that mammograms for women under 50 have not been proven to reduce mortality. And that's why we're here today.

I hope you can make some sense of NCI's new guidelines as you look into the decision-making process that produced them. But we are not here to referee between the experts on the effectiveness of screening mammograms for women under 40. Rather, we are here

to say that women need to know screening mammograms will be covered under health care reform. And we want to emphasize that women and their physicians must sort out what is best for them without worrying about who's going to pay for it.

I will let Congresswoman Slaughter talk to you about the specifics of our position. I have just tried to put the issue in some perspective.

It took years to get screening mammograms covered under Medicare, which we finally achieved in 1990. While they had been included in catastrophic coverage, that provision was quickly repealed. It took a threat on the House floor by our former colleague, Congresswoman Mary Rose Oakar, to bring down the budget if mammograms were not put back in. And, thankfully, they were.

What do women have to do this time to get the desperately needed research to determine if there are better ways to diagnose and treat breast cancer? At the very least, they need to be covered for one of the only screening devices available to them until something better comes along.

Today, you look at this one crucial aspect of women's health. But a much larger picture remains, and it still has too many gaps. Let's not let coverage of screening mammography for women under 40 be one of them.

Mr. TOWNS. Thank you very much for your testimony, and for the work that you've been doing on this issue.

Congresswoman Slaughter.

STATEMENT OF HON. LOUISE M. SLAUGHTER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Ms. SLAUGHTER. Thank you, Mr. Chairman. As Pat so eloquently put it, women in the country are obviously concerned. They are just beginning to realize how little the government cared about their health, and that we were not at all included. And one of the things that is most disturbing to me is that we are hearing that numbers of women in the country between the ages of 40 and 50 believing that the statistic is true are canceling their mammograms.

And one of the things that we want to make sure of this morning is that we try to get a message to them please not to do that. The preventive screening is critically important, and as Pat said, this afternoon we are going to be announcing the women's caucus position on screening for women 40 to 50.

But the debate has been terrible. We know that many distinguished scientists have questioned the efficacy of the ages 40 to 49. We know also that this is the age group where many cancers—the incidence increases within that age group.

While scientific evidence on each side is going to be discussed in great detail here today, the women's caucus was left to deal with a different problem. While we're fully aware of the fact that mammography in younger women may not have the value we wish, we can't say with any confidence that we have any effective detection method for breast cancer in younger women. The fact remains that mammography is all we have to offer. Women back in our districts suffering from breast cancer as well as those friends and loved ones who are fighting it with them, demand access to mammography no matter how uncertain a tool it may be. I understand that because, again, it is all that we have. As a matter of fact, in over 20 years the science of breast cancer has moved forward very little.

In order to clarify the coverage described in the Health Security Act, as well as setting the standard for all other health reform legislation that may come before us, the women's caucus is publicly announcing its consensus position on mammography coverage. Any health care reform plan should require insurers to provide free coverage of screening mammograms, every 1 to 2 years, for women aged 50 and older—which is what the President's plan recommends.

For women aged 40 to 49, where mammography has a less certain impact, but does help in earlier detection, insurance plans should cover screening mammography every 2 years, with copay and deductibles where they apply. But we insist that if there is a copay it be on a sliding scale and that no woman in the United States be left out of the peace of mind that she might get from a mammogram simply because she is not able to pay.

For women of any age, the plan should cover the annual clinical breast exam, which is different from the mammogram, and should cover, as well, the mammograms for any woman who is deemed at high risk for breast cancer at any age. This is the consensus position of the women's caucus and is what we're communicating to all

the House committees and subcommittees that are involved in health care reform.

Our position is very similar to that offered in your own "Sense of Congress" resolution, Mr. Chairman, for which we thank you. And I thank you once again for your support for women's health and the opportunity to come before you today.

I want to restate—because I don't want anybody to have any misunderstanding about this—the women in the United States have been left out of health research, and we know it. It's just been in the last few years that we've been able to get any. And as Pat said, Mary Rose Oakar stood on the floor many times to make sure that Medicare would cover mammograms.

I don't know how many years it took before I got here for her to even attempt that, but it was almost like trying to dock the Queen Mary by hand to get people to understand that it was necessary that Medicare cover that screening for older women. We have been—by climbing up the wall, by holding a handhold on the wall wherever we could get a little grasp, trying to explain to people that we watch this incidence of breast cancer rise in this country as it falls in other countries, and nobody knows why and no one can tell us why.

And now for us to even contemplate cutting out a fairly significant population of women in this country is simply a risk that we can't take. We would appreciate more studies, good clinical studies I think would be called for. But we are not at all satisfied, nor are many experts, as you know, satisfied that what the plan called for is going to be adequate to protect the health of the women in this country. And as women in Congress, we feel it is our obligation to stand up for all of those women and we do so today.

Thank you very much.

[The prepared statement of Ms. Slaughter follows:]

Rep. Louise Slaughter
Testimony before Rep. Towns' Subcommittee on Human Resources
3/8/94

Thank you for the opportunity to testify before your subcommittee, concerning preventive screening for women. The Congressional Caucus for Women's Issues, and the Task Force on Women's Health, have been examining this issue carefully, since last fall, when the President introduced his Health Security Act, and numerous other members offered their own versions of health care reform.

As you well know, there is currently a great deal of debate in the scientific and health policy communities surrounding the appropriate frequency for screening mammography, particularly for women under age 50.

Many distinguished scientists have questioned the efficacy of screening mammography in women between the ages of 40 and 49. For women over age 50, mammography has been shown to be effective in reducing mortality by as much as 30%. For women under 50, the results are less clear, leading the National Cancer Institute to make "no recommendation" about whether or not women in their 40's should be screened.

While the scientific evidence on each side of this question will be discussed in great detail today, the members of the Women's Caucus were left to deal with a different problem. While we are fully aware of the fact that mammography in younger women has only limited value -- in fact, we cannot say with any confidence that we have <u>any</u> effective detection method for finding breast cancer in younger women -- the fact remains that mammography is the best we have to offer. The women back in our districts who are suffering from breast cancer, as well as those whose friends and loved ones are fighting it: they all demanded access to mammography, no matter how uncertain a tool it is. I understand this; mammography is all they have. It is our obligation to provide this

coverage for all those who wish it.

In order to clarify the coverage described in the Health Security Act, as well as setting the standard for all other health reform legislation that may come before us, the Women's Caucus is publicly announcing its consensus position on mammography coverage.

Any health care reform plan should require insurerers to provide free coverage of screening mammograms, every one to two years, for women aged 50 and older.

For women aged 40 to 49, where mammography has a less certain impact on reducing mortality, but does help in earlier detection: insurance plans should cover screening mammograms every two years, with co-pays and deductibles where they apply. All co-pays should be sliding scale, so that a co-pay does not constitute a barrier to low-income women receiving care.

For women of any age, plans should cover annual Clinical Breast Exams, as well as mammograms for any woman deemed at high risk for breast cancer.

This is the consensus position of the Women's Caucus, and it is what we are communicating to all House committees and subcommittees involved in health care reform.

Our position is very similar to that offered in your own "Sense of Congress" resolution, Mr. Chairman, and co-sponsored by several Congresswomen.

I thank you, Mr. Chairman, once again, for your support for women's health, and for the opportunity to come before you today. I look forward to continuing our work to improve the health status of all American women.

Mr. TOWNS. Thank you, Congresswoman Slaughter. At this time I call on Congresswoman Snowe.

STATEMENT OF HON. OLYMPIA J. SNOWE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MAINE

Ms. SNOWE. Thank you, Mr. Chairman. I want to thank you for your leadership and for your statement, and Mr. Schiff's statement, as well, and your commitment and the sentiments that you have expressed here today, because that certainly is encouraging on this very important issue to women in America. I want to thank all of the subcommittee members here today.

I think, like all of my colleagues, I am shocked by the statements that have been issued by the National Cancer Institute suggesting that, in fact, experts do not agree on the role that routine screening mammographies can play, that they cannot really play a role in significantly reducing deaths in the age group of 40 to 49 for women.

One of the things that we have learned over the last few years at the Congresswomen's caucus is that women have not been treated equally in the health care arena, certainly when it has come to clinical study trials and women's health issues. And we've also learned that preventive care should be the hallmark of any health care reform for men and women, for that matter.

We know that an "ounce of prevention is worth a pound of cure." According to a commonwealth fund survey that was taken recently, one-third of all the women they interviewed said that they had not had any routine preventive care in the year before they were surveyed. The fact of the matter is women do not get good information from their doctors. There isn't sufficient public information about the steps that they can take toward preventive care, in general, that will prevent illnesses and diseases.

So now we're getting this message from the National Cancer Institute that somehow, based on inconclusive evidence, based on studies that did not include a significant number of women, poorly designed studies suggesting that somehow we'll take the imprudent course of action by not recommending screening mammographies for women in the age group 40 to 49.

In watching these videos here this morning it sort of made me think that the National Cancer Institute made this issue as clear as mud. I've never seen a more confusing mixed message that they're sending now as a result of rescinding these guidelines—even contradicting their own advisory committee 14 to 1, which indicated that the National Cancer Institute should maintain those guidelines.

That would have been the most prudent course of action until the National Cancer Institute had more conclusive studies, better clinical study trials. Why didn't they recommend more clinical study trials to see exactly what this was all about, rather than say, well, I guess, you know, saving, as we say here, 30 percent of women, their lives, that we're just going to say, "Sorry, it's not prudent for us financially." Because it is an economic decision.

Frankly, for that matter, we can make a lot of decisions. The least expensive course of action would be not to take any action at all. We know that. But the question is can we save lives. And we

have said we can't prevent breast cancer, but we can intervene to prolong women's lives. And we have worked over the last few years to put women's health issues on an equal footing, and this certainly sets it back in a lot of respects.

Now, I know the National Cancer Advisory Committee also recommended that the National Cancer Institute should get out of the guidelines business. I just thought it was the height of irony that they're starting with breast cancer. It sets us backwards, there is no question about it.

We have been trying to deal with the discriminatory behavior within National Institutes of Health in general, and we're trying to put women back on par with the men in this country in terms of the kind of support—financial support—and inclusion of women in clinical study trials, from which up until a few years ago, women were systematically excluded, along with minorities. That is clearly unacceptable.

In the 1990's, we can expect 2 million women to be diagnosed with breast cancer; 460,000 women will die from breast cancer, and 20 percent of those women will be in the age category of the forties. I can't imagine that we couldn't suggest to the women in this country that we wouldn't support screening mammographies for women in this age group.

And for that reason, Mr. Chairman, I am going to introduce a resolution asking the National Cancer Institute to rescind the guideline. That clearly is not the message. The premiere institute in the world, in terms of research, should not be in the position of making these kinds of statements about mammographies when we know they can save women's lives. So I think the only course of action is to make sure that they don't continue with this guideline, and rescinding it. Thank you, Mr. Chairman.

[The prepared statement of Ms. Snowe follows:]

Olympia J. Snowe
Testimony before the Committee on Government Operations
Subcommittee on Human Resources and Intergovernmental Relations
Hearing on The National Cancer Institute's Revision of its
Mammography Guidelines
Tuesday, March 8, 1994

Mr. Chairman, thank you for the opportunity to address this Committee today on the National Cancer Institute's revision of its mammography screening guidelines for women in their forties. As Co-chair of the Congressional Caucus for Women and as a woman, I want to express my extreme concern about the National Cancer Institute's statement that experts do not agree on the role of routine screening mammography for these women because randomized clinical trials have not shown a statistically significant reduction in deaths for women under age 50.

As we embark on health care reform, the Congressional Caucus for Women's Issues has been particularly mindful of the need for comprehensive health care for women. I am reminded of an old adage that an ounce of prevention is worth a pound of cure. A recent study has concluded that many women are not getting basic preventive care. More than one-third of the women interviewed by the Commonwealth Fund had not had any routine preventive care services in the year before they were surveyed. Women reported that they lack information from their doctors. Public information is sorely needed on how women can prevent and protect themselves against illness and disease.

Although the Board of Scientific Counselors for the NCI's

Division of Cancer Prevention and Control concluded that there was not a statistically significant benefit from routine mammography screening for women ages 40-49 after reviewing eight major studies, the National Cancer Advisory Board overwhelmingly voted to maintain existing guidelines. Nonetheless, the NCI chose to rescind guidelines for women in their forties based on what Dr. Broder stated were the "scientific facts."

That may be an accurate statement, but on what are these scientific facts based? On inconclusive evidence, on eight randomized clinical trials with too few women to prove a benefit for women in their forties. There have been no adequately designed and conducted studies of the benefit of screening mammography for women in this age group. For example, in the National Breast Screening Study of Canada, the only study designed to evaluate screening of women in their forties, the study was not completely blind and a disproportionate number of women with advanced cancers were allocated to the screening group, compromising the ability of the study to demonstrate a benefit for women in their forties.

According to Drs. Sickles and Kopans, physicians affiliated with the Departments of Radiology at the University of California School of Medicine in San Francisco and Massachusetts General Hospital and Harvard Medical School respectively, as well as 22 organizations, including the American Cancer Society, there is a

clear trend suggesting a benefit for screening women in their forties. There is an average 17 percent reduction in deaths in five of the randomized clinical trials having 10-12 years follow-up, despite deficiencies that would decrease the benefit.

In the 1990s, nearly 2 million women will be diagnosed with breast cancer and 460,000 will die. Seventeen to 20 percent of these women, approximately 92,000 women will be in their forties. Seventy to 85 percent have no known risk factors for breast cancer. What are we to tell them? We cannot prevent breast cancer, but we can intervene to save and prolong lives. Women who die of breast cancer lose an average of 20 years of life. Early detection and treatment can give back at least some of those years.

What are our choices? The least expensive option would be to do nothing. Should we allow thousands of women to die because of inconclusive research and inadequate communication? Should we tell women that although we know that early detection with screening mammography saves lives, we are waiting until we have foolproof scientific evidence? I reject this option.

I understand that the NCI considers itself a premier research institution. But, what kind of research are they performing? And on what are they basing their conclusions? Why, at this time, did they change their views, when there is no basis

for denying the potential effectiveness of screening mammography for women in their forties? Why did they not come out and support clinical trials for women in this age group?

I contend that a major reason is economic. It is less expensive not to routinely screen women in their forties. Instead of utilizing that ounce of prevention at their disposal, NCI has opted out of good sense and good science. Instead, it has changed its views based on inadequate evidence. For far too long, women have been shunted aside in medical research because of cost. This is no longer acceptable. With thousands of women dying of breast cancer each year, and with health care reform at its inception, we must assure women that adequate research will be conducted not only on finding a cure to end the scourge of breast cancer, but also on the effectiveness of early detection.

I call on the National Institutes of Health to rescind its recent statement for mammography screening of women ages 40-49 and continue to issue new guidelines when clear evidence warrants a change. Today I am introducing a sense of Congress resolution to advance this view.

Recently, the National Cancer Advisory Board passed a motion recommending that the NCI not involve itself independently in setting health care policy. When NCI rescinded its guidelines for women in their forties, a void in health care policy was

created. Within the government, decisions must be made as to how and where health care policy is set. Not only the quality but the length of lives depends on it. We must weigh in on the side of an ounce of prevention for women with breast cancer because we cannot afford to do otherwise. American women are entitled to no less.

Mr. TOWNS. Thank you very much, Congresswoman Snowe. I call on a former Member of the U.S. Congress who has been in the forefront for many, many years on this issue. We're delighted to see you. Welcome to the subcommittee, Congresswoman Oakar.

STATEMENT OF HON. MARY ROSE OAKAR, A FORMER REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Ms. OAKAR. Thank you very much, Mr. Chairman, and members of this very important committee, the investigative arm of Congress—and this is a good subcommittee to investigate this problem.

I want to compliment you, Mr. Chairman. All you have to do is read your resolution with the facts that are in the resolution and it says it all, that they were wrong and you're right. And I want to compliment Congressman Sanders, who did some wonderful work on the breast cancer registry a while back, and all the members for their eloquent testimony.

And my sisters—God love you, you're doing God's work again. I can't tell you how much this means to me, as a private citizen, to have this kind of leadership that is so needed, and I want to compliment you on what you said.

Mr. Chairman, I'd like to put my entire statement in the record and just make a few quick——

Mr. TOWNS. So ordered.

Ms. OAKAR. I think that this recommendation by NCI—and they do beautiful work there, so I am isolating my comments of criticism to this issue. They have some very dedicated people there.

But I think that their recommendation sets back the clock dramatically. Right now we have 43 States who mandate that private insurance and public insurance in their States have mammography once a year for women over 40, 40 and over. Some States even go back to the 1980 guideline of the American Cancer Society that says women over 35 should have a baseline mammogram. Personally, I think it should be women 35 and over.

So I think they set it back. And it wasn't just my feet on the House floor, it was the Congresswomen who in the caucus got together and said, "We have to stop this discrimination against women's health and minority health and all the other areas that are discriminated against."

But after that happened, when we were able to get some kind of coverage—and I'm not even satisfied with the coverage in Medicare, because it's once every other year at age 50 or over, or 40 or over if you're disabled. But once we did that then veterans benefits changed, CHAMPUS changed, FEHBP for Federal employees changed. All the other States passed legislation mandating mammography coverage. And now we're going to go backwards.

I want to address just one issue, and that is the issue of cost. Because everybody said, "Well, it costs so much." You're going to be debating whether every American has a right to comprehensive health care. What more noble debate can there possibly be? And if you don't put prevention and early detection in it, then you're missing a very, very major point, and that is this: That you not only save lives with early detection, you save a lot of money.

But you must estimate the cost savings over a 3- to 5-year period. If you only estimate it over a 1 year period, then of course,

if all the women who are 40 and over get a mammogram it's going to cost something more up front. But the savings that you make when you catch breast cancer in stage one or two—it costs $10,000 or less to treat that woman. It costs $165,000 or more if she gets an advanced breast cancer. And breast cancer costs more than $8 billion a year in private and public funding.

So we should be focused on the moral issue, and that is to save lives. But obviously, you have to get into the financial issue, and you can save a lot of money. And that ought to be the focus.

Finally, I want to go into a personal experience. Now, I wasn't going to do this, but I asked my niece's permission and she said I could.

About 3 weeks ago I and my niece, who is 37 years old, and I was 53, went to get a mammogram together at Georgetown Hospital. My mammogram showed that there was no problem. Hers showed—she's 37 years old—that there was some problem. She had a biopsy, and she has the earliest form of breast cancer. She will be, they tell me, completely cured when she undergoes the proper therapy because she caught it at a stage that is not even diagnosed, a stage I breast cancer, thanks to that mammogram.

She and her husband have a 5-year-old daughter. She will be able to go to her daughter's high school graduation, her daughter's college graduation. She would not be here if it weren't for that mammogram.

So I believe that you should go by what the Congresswomen said—what your resolution eloquently states, and at least provide a baseline mammogram for age 40. I would prefer that it start at 35.

But my niece Ann-Marie mirrors what thousands—29,000 women between 40 and 50 go through. So you can save money and lives by doing what is the moral thing to do. No health plan should not include mammography screening at the consensus age that is in your resolution and the Congresswomen's eloquent testimony. Thank you very much.

[The prepared statement of Ms. Oakar follows:]

STATEMENT OF THE HONORABLE MARY ROSE OAKAR
FORMER MEMBER OF CONGRESS
before the
HOUSE COMMITTEE ON GOVERNMENT OPERATIONS
SUBCOMMITTEE ON HUMAN RESOURCES AND
INTERGOVERNMENTAL RELATIONS

March 8, 1994

CHAIRMAN TOWNS, I AM HONORED TO BE HERE TODAY TO SHARE MY VIEWS ON THE NATIONAL CANCER INSTITUTE'S DECISION TO REVISE ITS GUIDELINES FOR SCREENING MAMMOGRAPHY. MR. CHAIRMAN, YOUR OWN LEADERSHIP IN CONGRESS HAS SERVED TO IMPROVE THE QUALITY OF LIFE OF SO MANY AMERICANS. THAT IS WHY I AM DELIGHTED THAT YOU HAVE TAKEN THE LEAD IN THE 103RD CONGRESS TO ENSURE THE ACCESS OF AMERICAN WOMEN TO LIFE-SAVING PREVENTIVE HEALTH CARE. I WAS PLEASED TO LEARN OF YOUR RESOLUTION TO REQUIRE THAT HEALTH REFORM INCLUDES A GUARANTEE OF AFFORDABLE, ROUTINE SCREENING MAMMOGRAPHY COVERAGE FOR WOMEN SIMILAR TO THE CONSENSUS GUIDELINES CURRENTLY RECOMMENDED BY MOST PROFESSIONAL HEALTH ORGANIZATIONS.

LET ME ALSO COMMEND OUR PRESIDENT AND MRS. CLINTON FOR THEIR STAND TO GUARANTEE EVERY AMERICAN ACCESS TO HEALTH CARE COVERAGE. AS THE ONLY FEMALE MEMBER OF THE 1988-1990 THE PEPPER COMMISSION ON HEALTH REFORM, I AM PLEASED THAT SO MUCH OF OUR REPORT FOUND ITS WAY INTO THE PRESIDENT'S PLAN. THE PREVIOUS PRESIDENT AT THAT TIME LOBBIED BITTERLY AGAINST OUR RECOMMENDATION THAT THERE WAS A EVEN NEED FOR REFORM -- FEW POLICY MAKERS NOW HOLD THAT VIEW. WHAT A BREATH OF FRESH AIR IT IS TO BE IN THIS POSITION TODAY DEBATING THE DETAILS OF A PRESIDENTIAL INITIATIVE THAT COULD PROVIDE EVERY AMERICAN WITH THE HEALTH SECURITY AND PREVENTIVE COVERAGE THAT OUGHT TO BE A RIGHT IN THIS COUNTRY. I AM GLAD THAT SCREENING IS INCLUDED IN THE PRESIDENT'S BILL, BUT I MUST TAKE EXCEPTION TO THE PROVISION AS DRAFTED WHICH LOWERS THE CURRENT STANDARD OF COVERAGE THAT I AND OTHERS FOUGHT HARD TO ACHIEVE. PRESIDENT CLINTON HAS SIGNALED THAT CERTAIN PROVISIONS OF THE BILL ARE NEGOTIABLE. I AM CONFIDENT THAT WITH THE FACTS BEHIND US WE WILL PREVAIL ON THIS IMPORTANT POINT.

MR. CHAIRMAN, AS YOU REQUESTED, I WILL DISCUSS "(MY) EFFORTS IN CONGRESS TO ELIMINATE COST BARRIERS TO BREAST CANCER SCREENING AND OTHER BREAST SCREENING METHODS, AND THE IMPACT THAT NCI'S RECENT CHANGE WILL HAVE ON (MY) LEGISLATIVE ACCOMPLISHMENTS, SPECIFICALLY THE IMPACT THAT THIS NEW CHANGE WILL HAVE ON

INSURANCE AND MEDICAID COVERAGE FOR MAMMOGRAPHY." NCI'S UNWARRANTED DECISION LAST FALL TO CHANGE THEIR RECOMMENDATION FOR WOMEN IN THE 40-49 AGE GROUP MAY SEVERELY UNDERMINE THE RECENT GAINS THAT BROUGHT RECORD NUMBERS OF MIDDLE AND LOW-INCOME WOMEN INTO MAMMOGRAPHY SCREENING PROGRAMS. WITH NO CONCLUSIVE NEW EVIDENCE, THIS DRAMATIC SHIFT SENDS A MIXED SIGNAL TO PROVIDERS AND WOMEN OF ALL AGE GROUPS ABOUT THE IMPORTANCE OF SCREENING MAMMOGRAPHY.

THE MAJOR PROBLEMS ARE AS FOLLOWS:

1. 25 PERCENT OF ALL NEW BREAST CANCER THIS YEAR WILL OCCUR IN WOMEN UNDER THE AGE OF 50 -- APPROXIMATELY 29,000 CASES IN THE 40-49 AGE GROUP.

2. NO CONCLUSIVE STUDY EXISTS TO PROVE OR DISPROVE THE VALUE OF SCREENING WOMEN IN THEIR FORTIES. YET THERE IS A GROWING BODY OF EVIDENCE THAT REGULAR SCREENING OF ASYMPTOMATIC WOMEN UNDER AGE 50 CAN DECREASE BREAST CANCER MORTALITY IN THIS AGE GROUP BY 13-24 PERCENT. MORE RECENT STUDIES INCLUDING A COMBINED SWEDISH TRIAL AND THE AMERICAN CANCER SOCIETY /NATIONAL CANCER INSTITUTE BREAST CANCER DETECTION DEMONSTRATION PROJECT INDICATE MARKED REDUCTIONS IN MORTALITY IN THE 40-49 AGE GROUP.

3.. BREAST CANCER MORTALITY IN THE U.S. IS GREATEST AMONG LOW-INCOME WOMEN AND AFRICAN AMERICAN WOMEN. THESE WOMEN, DESPITE RECENT GAINS ARE STILL LESS LIKELY TO BE SCREENED. LOWERING OUR STANDARDS AT THIS TIME WILL HAVE A DIRECT NEGATIVE IMPACT ON THIS GROUP OF AMERICANS.

4. THE CANADIAN STUDY WHICH PROVIDED THE IMPETUS FOR NCI CHANGE IS SERIOUSLY FLAWED -- A). THE STUDY DID NOT INCLUDE A STATISTICALLY SIGNIFICANT NUMBER OF WOMEN; B). THE LEAD INVESTIGATOR ADMITTED THAT THE EQUIPMENT USED WAS SUBSTANDARD EVEN FOR ITS TIME IN THE EARLY 1980s; C). THE STUDY WAS NOT CARRIED OUT FOR A LONG ENOUGH TIME TO SHOW A BENEFIT (SHOULD BE AT LEAST EIGHT YEARS); D). THE STUDY INAPPROPRIATELY INCLUDED WOMEN WITH ADVANCED STAGE BREAST CANCER, AND APPROXIMATELY 25 PERCENT OF THE CONTROL GROUP (SUPPOSEDLY NOT SCREENED) LATER ADMITTED THAT THEY WERE SCREENED DURING THE TEST PERIOD.

5. ASIDE FROM MY GENERAL CONCERNS ABOUT THE ORIGINAL NCI WORKSHOP WHICH RECOMMENDED THIS CHANGE IN GUIDELINES, A FOLLOW

UP NCI REVIEW CONSIDERED IT A MISTAKE TO CHANGE THE SCREENING RECOMMENDATION AT THIS TIME.

6. THE QUALITY OF BREAST IMAGING TECHNIQUES IS CONTINUALLY IMPROVING, RENDERING MOST STUDIES ALREADY DONE OUTMODED. WITH THE EMERGENCE OF STEREOTACTIC CORE BREAST BIOPSY AND BREAST MAGNETIC RESONANCE TECHNOLOGY, FOLLOW-UP AND DIAGNOSIS IS INCREASINGLY MORE EFFECTIVE AND ECONOMICAL.

7. LACK OF INFORMATION AND ENCOURAGEMENT ARE BARRIERS TO SCREENING. MOST WOMEN ARE NOT EDUCATED ABOUT THE IMPORTANCE OF SCREENING BY THEIR DOCTORS. CONSEQUENTLY, PHYSICIAN REFERRAL AND RECOMMENDATION ALONE IS PRESENTLY AN INEFFECTIVE METHOD FOR BRINGING WOMEN INTO SCREENING PROGRAMS. A CLEAR AND CONSISTENT GUIDELINE IS IMPORTANT.

8. COST IS A BARRIER TO SCREENING. INCREASED REIMBURSEMENT IN PRIVATE AND PUBLIC POLICY FOR THE BENEFIT, COMBINED WITH HEIGHTENED PUBLIC AWARENESS HAVE BROUGHT IN RECORD NUMBERS OF WOMEN. FORTY -THREE STATES NOW REQUIRE SCREENING THROUGH PRIVATE INSURANCE AND MOST ADHERE TO THE CONSENSUS GUIDELINES. NCI'S REVERSAL WILL SEVERELY UNDERMINE THIS TREND.

9. FEAR IS A BARRIER TO SCREENING. AT A TIME WHEN WOMEN ARE FINALLY FACING THE TRUTH THAT SCREENING CAN SAVE THEIR LIVES, NCI SEEMS TO BE SUGGESTING SOMETHING DIFFERENT.

10. FINALLY, BREAST CANCER INCIDENCE IS STILL INCREASING. ONE IN EVERY EIGHT AMERICAN WOMEN MAY NOW BE DIAGNOSED WITH BREAST CANCER IN THEIR LIFETIME. BREAST CANCER REMAINS THE NUMBER ONE CAUSE OF NON-PREVENTABLE CANCER DEATHS IN AMERICAN WOMEN. AS DR. REBECCA ZUURBIER, DIRECTOR OF CLINICAL BREAST IMAGING AT GEORGETOWN MEDICAL CENTER OBSERVES, "WE CANNOT PREDICT OR LEGISLATE THE BIOLOGIC ACTIVITY OF CANCER, BUT WE CAN SAVE MONEY AND LIVES BY INCREASING, NOT REDUCING, WOMEN'S ACCESS TO REGULAR MAMMOGRAMS."

NO ONE IS MORE DISAPPOINTED THAN I AM AT THE RECENT RETREAT OF THE NATIONAL CANCER INSTITUTE (NCI) FROM ITS MAMMOGRAPHY SCREENING GUIDELINES FOR WOMEN AGES 40-49. THE SHIFT IN NCI RECOMMENDATIONS HAS ALREADY SERVED TO UNDERMINE ACCESS TO SCREENING IN MANY OF THE HEALTH CARE PROPOSALS BEFORE CONGRESS. I

HAVE ALWAYS BEEN ONE OF NCI'S MOST ARDENT SUPPORTERS IN CONGRESS. IN 1989 WHEN DR BRODER HAD A RELATIVELY MEAGER BUDGET TO SPEND ON RESEARCH TO FIND A CURE AND IMPROVE EARLY DETECTION FOR BREAST CANCER, I CONVINCED THE SELECT AGING COMMITTEE TO HOLD THE FIRST HEARING IN THE HISTORY OF THE U.S. CONGRESS SPECIFIC TO BREAST CANCER RESEARCH. I ALSO INTRODUCED THE FIRST LEGISLATION SPECIFIC TO BREAST CANCER RESEARCH IN 1989. TODAY THE FEDERAL COMMITMENT TO BREAST CANCER RESEARCH IS FIVE HUNDRED PERCENT OF THE 1989 FIGURE AND OUR EFFORT NEVER ONCE COMPROMISED THE OTHER IMPORTANT WORK AT THE NCI. I WILL CONTINUE TO SUPPORT THE SCIENTISTS OF THE NATIONAL CANCER INSTITUTE, BUT I AM BITTERLY DISAPPOINTED AND AT A LOSS TO UNDERSTAND THEIR RECENT SHIFT IN SCREENING GUIDELINES FOR WOMEN IN THE 40-49 AGE BRACKET.

THE NCI'S DECISION TO BACK OFF A STRONG RECOMMENDATION FOR SCREENING IN THIS AGE GROUP AT A TIME WHEN WOMEN ARE AVAILING THEMSELVES TO SCREENING IN RECORD NUMBERS SENDS A MIXED SIGNAL. FOURTEEN HIGHLY RESPECTED NATIONAL PROVIDER AND RESEARCH ORGANIZATIONS RALLIED BEHIND THE 1989 CONSENSUS RECOMMENDATIONS WHICH BECAME THE STANDARD FOR MOST GOVERNMENT AND PRIVATE PROGRAMS NOW IN PLACE. THIS BROAD PROFESSIONAL CONSENSUS ON WHO SHOULD BE SCREENED SERVED TO STRENGTHEN MY HAND THAT YEAR NEAR THE CLOSE OF MY SIX YEAR EFFORT TO CONVINCE MY COLLEAGUES THAT SCREENING FOR BREAST CANCER BE INCLUDED IN MEDICARE POLICY. IT ALSO STRENGTHENED THE HAND OF HUNDREDS OF LOCAL ORGANIZATIONS AND PROVIDERS IN NEARLY EVERY COMMUNITY IN THE COUNTRY WHO STRIVE TO ENCOURAGE WOMEN TO TAKE ADVANTAGE OF THE BENEFIT. NCI IS THE ONLY SCIENTIFIC ENTITY TO SPLIT FROM THIS CONSENSUS GROUP.

FOLLOWING MY SUCCESS AT THE CLOSE OF THE 101ST CONGRESS IN WINNING COVERAGE UNDER MEDICARE , THE FIRST PART OF THE 102ND CONGRESS SAW PREVENTIVE MAMMOGRAPHY BENEFITS ADDED TO THE FEDERAL EMPLOYEE HEALTH BENEFITS PROGRAM, THE MILITARY'S CHAMPUS PROGRAM, THE VETERANS ADMINISTRATION HEALTH SYSTEM. IN ADDITION THE 102ND CONGRESS ENACTED THE CDC BREAST AND CERVICAL CANCER MORTALITY INITIATIVE FOR LOW INCOME WOMEN, AS WELL AS UNIFORM NATIONAL GUIDELINES FOR MAMMOGRAPHY SCREENING QUALITY AND EFFECTIVENESS. THE TOTAL NUMBER OF STATES WHICH REQUIRE SCREENING IN INDIVIDUAL PRIVATE HEALTH INSURANCE HAS INCREASED TO 43. ABOUT ONE-THIRD OF THESE STATES ENACTED LEGISLATION IN JUST THE LAST FEW YEARS. IT IS IMPORTANT TO NOTE THAT THE VAST MAJORITY OF THESE STATE REQUIREMENTS ARE CONSISTENT WITH THE CONSENSUS GUIDELINES WHICH RECOMMEND REGULAR SCREENING FOR ASYMPTOMATIC

WOMEN IN THE 40-49 AGE GROUP.

PHYSICIANS CURRENTLY DO NOT RECOMMEND SCREENING OFTEN ENOUGH FOR ALL WOMEN, EVEN FOR WOMEN WITH SIGNIFICANT RISK FACTORS. THE NEW NCI RECOMMENDATION RELIES ON THE IDEA THAT PHYSICIANS WILL RECOGNIZE WOMEN WITH HIGH RISK FACTORS AND MOVE THEM INTO SCREENING PROGRAMS FOR WHICH THEY ARE UNLIKELY TO RECEIVE REIMBURSEMENT IN THE FUTURE. IN ANY COST CONTAINMENT PROGRAM THAT IS DRIVEN BY MANAGED CARE , WHEN A PHYSICIAN DOES RECOMMEND SCREENING FOR A WOMAN UNDER AGE 50, ONE CAN BE CERTAIN THAT REIMBURSEMENT FOR THIS BENEFIT WILL BE FREQUENTLY DENIED AS A RESULT OF NCI'S IMPLICATION THAT YOUNGER WOMEN DON'T REALLY NEED A MAMMOGRAM.

TO THE 43 YEAR OLD WOMAN WITH A KILLER TUMOR IN HER BREAST, A TIMELY MAMMOGRAM WILL NOT ONLY SAVE HER LIFE , IT WILL SAVE THOUSANDS OF DOLLARS IN ADDITIONAL CANCER TREATMENT COSTS. IT ALSO SAVES HER FAMILY FROM THE COSTS ATTENDANT TO CHRONIC DISEASE IN THE FAMILY. BESIDES THE PATIENT'S OWN LOST PRODUCTIVITY, MANY OTHER EXPENSES ARE INCURRED SUCH AS REQUIRED COUNSELING, TRAVEL EXPENSES, AND DAY CARE SERVICES. A SUCCESSFUL MAMMOGRAM MAY GIVE THIS YOUNG AMERICAN TWENTY, THIRTY, PERHAPS FORTY YEARS OF CONTINUED VITALITY AND PRODUCTIVITY FOR HER FAMILY AND HER COMMUNITY.

FROM THE TIME OF THE FIRST HEARINGS ON WHETHER MAMMOGRAPHY SHOULD BE INCLUDED IN MEDICARE, WHICH I CALLED FOR IN THE EARLY 1980s, I HAVE STRUGGLED TO POINT OUT THAT CBO, OMB AND CONGRESS' ANNUAL BUDGET PROCESS DO NOT BEGIN TO CALCULATE THESE LONG-RANGE SAVINGS FROM PREVENTIVE CARE. A 1985-1989 STUDY BY DRS. HODGSON AND RICE , SUPPORTED BY THE CENTERS FOR DISEASE CONTROL, DID MAKE THIS ATTEMPT AND FOUND THAT IN 1990 BREAST CANCER MORTALITY COST OUR NATION OVER $8 BILLION DOLLARS. LOOKING ONLY AT MEDICAL COSTS, WHEN AN AMERICAN WOMAN DIES OF BREAST CANCER IT COSTS AT LEAST $160 THOUSAND -- OFTEN MORE. AS A MEMBER OF THE PEPPER COMMISSION ON HEALTH CARE REFORM, I WAS ABLE TO CONTRAST THIS BY SHOWING THAT A CANCEROUS BREAST TUMOR DETECTED IN ITS EARLIEST STAGES COSTS, ON AVERAGE, $10-15 THOUSAND TO TREAT WITH VASTLY IMPROVED PROSPECTS FOR A LONG, PRODUCTIVE LIFE. SUBSEQUENTLY, THE COMMISSION ACCEPTED MY RECOMMENDATION THAT COVERAGE FOR ANNUAL SCREENING MAMMOGRAPHY BE INCLUDED IN ANY HEALTH CARE REFORM.

EVEN WHEN I DID CONVINCE MY COLLEAGUES TO ENACT MEDICARE COVERAGE FOR ELDERLY AND DISABLED WOMEN IN 1989, I WAS FORCED TO COMPROMISE AND THE BENEFIT WAS ONLY AVAILABLE TO MOST WOMEN EVERY OTHER YEAR. THIS CAUSED SOME DIFFICULTY IN STATES THAT HAD ALREADY IMPOSED REQUIREMENTS FOR ANNUAL COVERAGE IN PRIVATE INSURANCE POLICIES. HCFA WOULD NOT PERMIT PRIVATE REIMBURSEMENT FOR THESE WOMEN IN THE BETWEEN YEARS. I FEAR THAT IN LIGHT OF THE NEW NCI GUIDELINES, WE WILL SEE STATE AND FEDERAL PROGRAMS CUT BACK ON SCREENING FOR WOMEN IN THE 40-49 AGE GROUP AS A PENNY WISE AND POUND FOOLISH BUDGET CONSIDERATION.

MR. CHAIRMAN, IN YOUR INVITATION YOU ASKED ABOUT THE IMPACT OF THESE NEW NCI GUIDELINES ON LOW AND MIDDLE INCOME WOMEN. ON OCTOBER 1, 1992 I CHAIRED A HEARING OF THE HOUSE SELECT AGING COMMITTEE SUBCOMMITTEE ON HEALTH APTLY ENTITLED, "BREAST CANCER: WINNING THE BATTLES, LOSING THE WAR." THIS HEARING WAS, AMONG OTHER THINGS, A PROGRESS REPORT. A STUDY WAS PRESENTED THAT DAY BY THE JACOBS INSTITUTE FOR WOMEN'S HEALTH ON TRENDS IN ACCESS TO MAMMOGRAPHY SCREENING. THE STUDY FOUND THAT ALTHOUGH ACCESS HAS INCREASED DRAMATICALLY, SOME OF THE HIGHEST RISK GROUPS INCLUDING LOW AND MODERATE INCOME MINORITY WOMEN WERE STILL NOT GETTING INTO THE PROGRAMS. THE STUDY FOUND THAT LACK OF MONEY AND THE LACK OF UNDERSTANDING ABOUT THE NEED FOR A MAMMOGRAM WERE THE TWO GREATEST BARRIERS TO ACCESS. THESE FACTORS, COMBINED WITH THE INHERENT FEAR WOMEN HAVE ABOUT BREAST CANCER, KEEP MILLIONS OF WOMEN OUT OF SCREENING PROGRAMS. ADD TO THAT THE FINDING THAT FORTY PERCENT OF WOMEN SURVEYED INDICATED THAT THEIR PHYSICIAN HAD NEVER RECOMMENDED OR EVEN DISCUSSED THE MATTER WITH THEM. I TAKE NO COMFORT IN THE NCI SUGGESTION THAT PHYSICIAN COUNSELING IS SUFFICIENT FOR WOMEN IN THE 40-49 AGE GROUP.

MR. CHAIRMAN, ANOTHER WITNESS AT THAT HEARING, ONE OF MY FORMER CONSTITUENTS, TESTIFIED THAT AT THE AGE OF 40 SHE WAS DIAGNOSED WITH BREAST CANCER AFTER SHE NOTICED A LUMP IN HER BREAST. SHE WAS NEVER ADVISED TO HAVE A MAMMOGRAM ALTHOUGH AN EARLIER BASELINE MAY HAVE SAVED HER BREAST. SHE IS LUCKY TO BE ALIVE TODAY, EVEN THOUGH SHE ALSO LOST HER HEALTH INSURANCE THROUGH THIS PROCESS. NO ONE NOW CAN CONVINCE THIS WOMAN THAT WOMEN AT FORTY SHOULD NOT HAVE A MAMMOGRAM. HER EXPERIENCE MIRRORS THE EXPERIENCE OF THOUSANDS OF WOMEN IN THIS AGE GROUP EACH YEAR. TOO MANY ARE NOT SO LUCKY.

MR. CHAIRMAN BREAST CANCER REMAINS ONE OF THE TOP CAUSES OF

DEATH AMONG WOMEN IN THIS COUNTRY. SOME 30,000 CASES EACH YEAR STRIKE THE 40-49 AGE GROUP ADD TO THAT THE FACT THAT BREAST TUMORS MAY OFTEN BE MORE AGGRESSIVE IN YOUNGER WOMEN. YOUNGER WOMEN HAVE EVEN GREATER FEARS ABOUT THE PHYSICAL AND EMOTIONAL RAVAGES OF THIS DISEASE. THIS REALITY ALONE KEEPS MANY OF THEM FROM GETTING A MAMMOGRAM AND COSTS MANY OF THEM THEIR LIVES.

THE NCI SHOULD CONTINUE AN AGGRESSIVE CAMPAIGN OF RESEARCH TO FIND A CURE AND IMPROVE EARLY DETECTION TECHNIQUES. IMAGING TECHNIQUES HAVE IMPROVED DRAMATICALLY IN RECENT YEARS AND MANY EXCITING NEW TECHNOLOGIES ARE NEAR AT HAND. NCI SHOULD BE MORE ADEQUATELY FUNDED IN THIS FIGHT. IN THE MEANTIME, THEY MUST REVERSE THIS ILL-ADVISED SHIFT IN SCREENING GUIDELINES. WHILE NCI SEEMS CONVINCED THAT THERE IS NO OVERWHELMING EVIDENCE TO SUPPORT REGULAR SCREENING IN THIS AGE GROUP, THEY STILL CANNOT CITE OVERWHELMING EVIDENCE AGAINST IT. FINALLY, I COMMEND THE HEALTH PROFESSIONALS AND CONSENSUS ORGANIZATIONS WHO CONTINUE TO SUPPORT THE RECOMMENDATION THAT WOMEN OVER 40 SHOULD BE SCREENED REGULARLY.

THANK YOU AGAIN, MR. CHAIRMAN, FOR THE OPPORTUNITY TO SPEAK ON THIS SERIOUS MATTER. AGAIN, I COMMEND YOUR LEADERSHIP ON WOMEN'S HEALTH ISSUES. I HOPE THAT WE CAN CONTINUE TO WORK TOGETHER. I LOOK FORWARD TO ANY QUESTIONS THAT YOU AND THE MEMBERS OF THE SUBCOMMITTEE MAY HAVE.

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Mr. TOWNS. Thank you. Let me thank all of you for your testimony, and for your support of my resolution. I think that you've said it so well how important it is that we all must work together on these issues.

And I want to assure you, that I am committed to this issue—on a personal note, I come from a family of four originally, where my father died of cancer, and my mother, I lost her to cancer, and my younger brother also to cancer, and I'm on a watch myself. So when you talk about cancer and anything that we can do to prevent it, you can be assured that I'm there.

At this time I would like to yield to Congressman Schiff for any comments that he might have.

Mr. SCHIFF. Thank you. First of all, Mr. Chairman, I very much appreciate Representative Oakar's mentioning a personal experience, family experience, because I think that the people that are with us today need to understand that even if we're in Congress, we still have families and have the same family considerations, concerns, experiences that everyone else does.

My paternal grandmother died of breast cancer some decades ago now at this point, so I understand what's being said today.

I'd like to raise two questions for whatever response the panel might give. I think we've touched on both these. But the first is, I'm concerned about the fact that the direction of the National Cancer Institute may have gone may be reflective of the fact that in the setting of medical standards, men and women are not evaluated separately or treated equally. And I think I hear that come up over and over again.

Ms. SLAUGHTER. We're used to that.

Mr. SCHIFF. And would invite—particularly from the congressional women's caucus, would invite any of the panelists who might want to comment on the accuracy of that fact to do so.

Ms. SLAUGHTER. Well, you're absolutely accurate. We have not been treated equally, and one of the reasons we found about it was the aspirin study, and that was a real eye-opener to us because we were told that an aspirin a day could help men prevent stroke and heart attacks. And we said, "Wonderful. It's really great. And every man we know is going to do this. Now, how much do we take?" And we got a blank stare.

There was always sort of a charge that—you know, we were out of the same species, but not quite, and maybe they could adjust a bit there.

But at the same time diseases and problems that affect only women were almost unheard of. For example, let me give you a story on this one that I like to talk about, and that's the diethylstilbestrol which was given to pregnant women in the United States for about 40 years.

In 1935 the Department of Agriculture said that it could not be used for cattle anymore because it caused reproductive difficulties. But it was given to American women who were pregnant then for 40 years on the theory it would prevent miscarriage. Now, during those years there was no study done to see if that was the case, except one, I think, at the University of Chicago that showed that bedrest was just as efficient to prevent miscarriage as DES.

In the 1970's they found out that numbers of daughters of DES mothers were evidencing clear cell cancers, cancers of the uterus and vagina, reproductive systems, many other problems, many of them dying very early, and almost none of them able to have children of their own. And we also found that the women who had taken DES were much more prone to breast cancer and other diseases as well.

Now, no study has been done on this to any extent at all. As a matter of fact, people who have been affected by DES are not even notified that they might be in line for a higher incidence of cancer than other people in the population.

We've managed in the last couple of years to put just a little bit of money in there, but we also—all of us understand that women also have sons, and we looked at whether or not DES sons were not also part of this population. And I have one colleague here—we all do—who believes that the problems that he has had in his life were probably due, in part, to the fact that his mother was also given DES.

Ovarian cancer, to this day, is almost a diagnosis for death. And men have a blood test for prostate cancer. Ovarian, as I said, almost—you have to be almost in the final stages before they discover it. We didn't think there was very much done on cancer of the cervix. Osteoporosis costs, I think—I hope I've got this right—about $20 billion a year to treat, and not a dime was spent on it. It's basically a disease of women.

So in 1990 we got together and we put some money into the budget and said we would like an Office of Women's Health—not because we wanted to be treated any special way, we simply wanted to try to catch up.

Mrs. SCHROEDER. We just want to be treated.

Ms. SLAUGHTER. We want to be treated, right. And the fact of the matter is—you know, when we look at breast cancer—and let's really look at this—the incidence of breast cancer in the United States is growing. Three hundred men will die this year, incidentally, of breast cancer.

Now, when it's one in nine, as it is now, and headed toward one in eight, there isn't a family in this country that hasn't been touched by this in enormous ways. And the fact that we're seeing women younger and younger with breast cancer—as Mary Rose points out, women with children. I mean, the devastation on the family—I mean, you may think about this if you think about it in financial terms, but think of it in human terms, and the fact that we just didn't do it.

Now, we understand that one of the big questions was hormones, but we've always had them, and so you would think that by now in this century that there could have been some sense to, well, all right, they have got hormones over there, but we love them and we need them, and we will try our best to keep them alive. So that's what we've been striving for.

I don't mean to put it in that lowest common denominator, but it's the absolute truth. We were simply left out. That's why this frightens us so much. We don't want to send a message to the women in this country that we're about to retreat in any way. And I agree with Mary Rose. NCI does some wonderful work. And I cer-

tainly agree with Olympia that we've been worried about NIH for a long time, and we have legislation, indeed, to find out what happens to women scientists there.

We also have some legislation in to see if any of these cancers have any—or are attached in any way to the use of pesticides. But we may think it's a familial cancer when three sisters have it, breast cancer. It may also be because they were all exposed to DDT.

We don't know these things, and so we're just asking for a little consideration and——

Mrs. SCHROEDER. Mr. Schiff, if I could just add one thing. The caucus has been monitoring this forever and ever, and some of us discovered this in the mid-1980's, that there were no women in any of the studies.

We went over and met with NIH, and they promised, it was like, "Oh, what an oversight." You know, it would all get better.

And then we kept saying, "Well, you know, we keep reading these stories about men eating fish, men on aspirin, men and aging, men and this, men and"——

Ms. SLAUGHTER. Men and stress, men and high blood pressure, men and heart.

Mrs. SCHROEDER. We kept saying, "Does that mean women?"

Ms. SLAUGHTER. Nobody knew.

Mrs. SCHROEDER. And we had another GAO study, and it said, no, they hadn't moved an inch. So we got very angry and then started doing the legislation. And I remember very well going out and saying, "In your aging study you had 75,000 people, the largest study ever done. Not one woman in it." So they know nothing about frailty, osteoporosis, menopause, any of the other things.

And the frustrating thing is, women contribute equally in that tax base. That's all funded with tax dollars. But they have been totally ignored. And it looks like when we get to health care services—they've been ignored in the research, they want to ration it to us, but they're not talking about rationing it to men.

And I think America's women are tired of this, and that's exactly what we're saying.

Ms. SNOWE. I understand that the National Institutes of Health actually violated its own policy by systematically excluding women and minorities from the clinical study trials, and it was the famous aspirin study that included 22,000 white male physicians and no women.

So we passed the legislation to require them to pursue their own policy of including women in those clinical study trials as well as minorities. But they, basically, up to that point, were not, because it was inconvenient. They were not willing to accommodate the biological differences in order to include women in those clinical study trials. And, hopefully, that's changed.

Mr. SCHIFF. Mr. Chairman, I wonder if you might yield an additional couple of minutes to me. I have one more question.

Mr. TOWNS. I'd be delighted to.

Mr. SCHIFF. I thank you, Mr. Chairman. Once again, I'm going to throw out an observation and invite the panel to agree or disagree as they will.

I'm concerned that, over and above the gender differences, which are a concern enough, that you've described, that when any approach—and it doesn't matter to me which side of the aisle the approach may come from—has spending targets as part of its—a necessary part of its approach, that that encourages the medical community, especially that apparatus of it that works for the government, to set the medical guidelines that fit the spending targets, rather than the other way around, whether it's on this subject or any other subject.

I think that's a severe drawback of having spending targets, because we might proverbially try to get the square peg into the round hole in order to make everything fit. And I wonder if you would comment on that.

Mrs. SCHROEDER. Well, I think people are concerned about that. The question on this is which is the chicken and which is the egg. Did NCI do this to try and come in under a spending target, or did they do this on a folly of their own? And I don't think we know that answer.

But, clearly, the message to women is, if there are tight budget targets, and the system remains the way it is now, you're going to fall off when it comes to health care, because the majority will fund what they fear, and they don't fear getting breast cancer. So they'll say, "Well, we'll do away with mammograms." And that's a very tough thing to say, but I'll tell you, we have the experience of 10 years of working in this field, and we have seen it over and over again.

So the spending targets will be imposed on women first, and rationing will be on women first, unless we are really, really watching.

Ms. SNOWE. I know my first reaction was—when I heard about the NCI statement on the guidelines for women in their forties—is that this was more than coincidence, that it had something to do with health care reform, economic issues and saving money. I think there's no question it's driven by these issues.

And that's something that we're going to have to be very cautious about in this health care reform debate and what kind of policies we exact, and I think that's basically what the American people are concerned about, to establish those global targets, whether or not we're going to be rationing health care, and who's going to be the first affected by that rationing.

Ms. OAKAR. Could I just comment on that? I would like to make a distinction, though, between targets and caps. I think you can place a cap on the cost of a mammogram and say that you will not pay more—government or whoever will not pay more than $55, because you can do it for that amount and less.

Dr. Strax, in New York City charged $35 because he has thousands and thousands of women taking advantage of that mammogram. So there has to be a distinction made in terms of what you will spend out because you will reduce the cost if you have more women taking advantage of what will be early detection for them.

The other point that I want to reemphasize is that you have to estimate what you will save over a longer period than 1 year. And here you estimate things—the Congressional Budget Office used to debate with me all the time about what this would cost if we put

this in Medicare because they estimate over a 1-year period. If you estimate on what you save when you find breast cancer at an early stage, you're going to save thousands and thousands of dollars.

And one last point. The chairman has been afflicted—his family has been afflicted by cancer. Breast cancer is an epidemic for white women. It is more than an epidemic for black women. And what does this say when you have a study that is faulty that does not mirror the population of the United States of America? You're saying that, in fact, we're leaving out—you may not intend to say that, but that's the signal it gives—that we are really not going to have a study based on American women. We're going to have a study based on women who don't have the populations of minorities that we do in this country. And that's why it's especially acute toward black women and especially unreasonable.

So let's give the right message and reemphasize the old guidelines and tell American women to have that mammogram. It will save their life and save a lot of money.

Ms. SLAUGHTER. Mr. Chairman, if I could make just one more point, and that is, one of the other important aspects of this is the person who reads the mammogram and the machine on which it is given. And we have worked here for years to get standards so that there would be standardization of every mammogram machine, and that we would be sure the readers were certified.

That's also been a serious problem, I think, that's been associated with breast cancer, and, again, that's taken, what, 6, 7 years, and we still have not achieved that. I mean, we just finally got all that passed into the Senate.

But that, again, is something that's of great concern to women, as to whether or not when they get it, can they have that peace of mind that it's accurate?

Mr. SCHIFF. Mr. Chairman, I want to thank the panel again.

Mr. TOWNS. Thank you. It's time I yield to Congressman Sanders.

Mr. SANDERS. Thank you very much, Mr. Chairman, and I really want to congratulate all of my colleagues for the excellent testimony that you gave and you, Mr. Chairman, for holding this important meeting. I also want to thank Mary Rose Oakar very much for the help she gave me last year in getting the cancer registry through.

I would just make a couple of points and ask some questions. The issue of cancer is an enormously difficult and painful issue, as we've heard from everybody. And God knows that everybody wants to begin to get to the root of the problem in understanding what is causing this epidemic.

But I just want to start off with a short, simple question. While we have enough problems trying to understand the cause of cancer, it would seem to be an absolute unacceptable outrage that within Federal agencies we are still dealing with sexism or racism or any of that old crap. It is hard enough to begin to deal with the root of the problem.

We have men's problems in cancer, we have women's problems, minorities have special problems. These are difficult problems that honest people are having a hard time dealing with.

If, in fact—I mean, it is almost—to be very honest with you, difficult for me—I hear what you're saying, and I accept what you're saying, but it is almost difficult to comprehend that in the 1990's we're still talking about old-fashioned sexism, that we don't spend money on women's health needs as opposed to men's health needs. I know that that is a fact, what you're saying is accurate.

But let me just state it—you state clearly for the record, and tell me if you think this kind of blatant sexism still exists. Have we targeted the people who are guilty of this, and have we gotten rid of those people? Because while we have enough problems getting to the root of the problem, we don't have to accept sexism or racism in the government anymore.

So let me be very blunt with you. Who is doing this, and what are we doing about it? Anybody?

Mrs. SCHROEDER. Mr. Sanders, we can say that we did pass a bill this year, and President Clinton signed it, that will put in an office of women's research and so forth. We're still working on trying to get more women into NCI and into all the National Institutes of Health and into scientific roles, because they're not there. It's been a great ole boy's club.

And if we took your advice and fired everybody, there wouldn't be anybody left, almost. Because it really has been a cultural thing, where they didn't understand what was happening.

I remember being over there meeting with the heads of the different institutes, and we had Senator Barbara Mikulski, Connie Morella, and I meeting with them. A couple of them got up and said, "We're going to go to lunch," and walked out, and Senator Mikulski stood up and said, "You would never do this to a male Senator, you would never do this to a male Representative. What is this stuff? Come back here and sit down."

Well, it was like they were offended we were there, how could we have come out, what were we talking about? And it's such a cultural thing, it's like we've been interfering in their science, we've been accused of micromanaging, we've been accused of everything.

Mr. SANDERS. I mean, cultural, schmultural, we are in the 1990's, and I think, Mr. Chairman, that we might want to look at this and find that—again, the issue of cancer is a very difficult one, and honest people have differences of opinion. But on the issue of sexism, we've gone a little bit too far to tolerate that type of behavior. And if they can't catch on to what's going on in the 20th century, they really should not be working for the U.S. Government, and I think we should take a look at that.

Ms. SLAUGHTER. Bernie, if you remember, it was only 2 years ago that the NIH bill was vetoed, partly on the recommendation of the head of NIH that closed the Office of Women's Health.

Mr. SANDERS. Let me ask another question, and that is, some of us seem to be dealing with a great deal of pain with agencies like the FDA and the EPA. It is often acknowledged, and recent reports seem to indicate—Dr. Debra Davis came out with a very disturbing report on the growth of cancer—that, in fact, we are losing the war on cancer that Nixon started in the 1970's.

Generalizing the debate, the discussion a little bit, has the Federal agencies, the NCI, in your judgment, been as innovative and bold, understanding that we're dealing with an epidemic? You

know, if we keep doing the same thing every year and we continue to lose, maybe it's appropriate to broaden our discussion.

And there's a whole lot of new thinking, as you're all aware of, on the issue of diet, on the issue of stress, on occupational health. Are we doing those studies, to know—I have seen some studies. People working in certain professions come down with higher rates of cancer than other people.

Has, in your judgment, in terms of breast cancer, the NCI been doing as good a job as they should, in taking a broad look perhaps at some of the research that's going on?

Ms. SLAUGHTER. Bernie, I think we starve medical research in this country. And one of the things that you can't do is turn research on and off like a faucet. And you can't fund it 1 year and cut it the next.

And this is only my opinion, but as a former microbiologist, it appears to me, in the time that I've been in Congress, that the preoccupation in the U.S. Government with women's reproductive systems was so strong that it really drove what kind of research was possible and what kind of research was not possible. And that had an awful lot to do, I think, with putting us behind in some of the research we've been able to do.

RU–486, for example, we know had some efficacy in brain tumors, and other things that it could have been used for but we were not allowed even to discuss it or to bring it into the country.

So partly it's been philosophical, but I think that we have been losing that battle, and that we—it seems to be taking forever to get anything done. But I don't blame that really on the National Institutes of Health as much as I blame it on the fact that we just simply didn't pay enough attention there; nor did we follow the kinds of—I don't want to micromanage it, and I don't really want to say what they need to be doing over there, but have they been innovative?

I don't know. I don't think so. But perhaps the reason is that they didn't have the money to be able to do so, and that would come back to us, what our priorities are in America.

Mrs. SCHROEDER. Bernie, I have an idea for you that I need some people to help me with, and that is when you look at the Defense Department, there's a very interesting statistic. It appears that people who were in the military seem to have a higher incidence of cancer.

I don't think we've done enough research, and there is a terrific body of records. If we can get them the money to stop doing Star Wars and start doing cancer wars, we might really find something out.

I do think there's some environmental impact that we haven't had time to look at.

Mr. SANDERS. We don't even know—one of the reasons that we worked on this National Cancer Registry, it is insane that in a Nation of this development, we don't have the statistics on everybody who's getting cancer. Where are they living? Where are they working? What is their background?

I mean, that's obvious A, B, C stuff, and it's not an expensive proposition.

Ms. SLAUGHTER. Think back to the DES that I told you about a while ago. We have third generation children, some of the children who were able to have their own children, that have problems. And it would seem to me that what we've been trying to find out forever: is there a genetic link in cancer?

Now, this is a laboratory, it seems to me, that's out there throughout the country. It would be very important to know what has happened to all the offspring of the women who were given DES. But nothing has been done about that, even a registry, as you point out.

Ms. OAKAR. Congressman, can I just point out I think she believes and the Congresswomen are dead right about what is the slow movement, and so forth.

I would like to say, however, that I think, when you consider that breast cancer only got $25 million, I think 4 years ago, for clinical trials, when AIDS research, and I'm all—I was all for it—got $1.3 billion, and I don't say take it out of AIDS research. I say you have $35 billion for the defense research for new weaponry. All of NIH only gets $9 billion. Give them another billion.

And you know, they are doing some important things. And one of the things that they have opened, thanks to many of you in Congress, is the alternative medicine department——

Mr. SANDERS. All of $3.5 million, I think, right? It's a start.

Ms. OAKAR. Right, but at least it's there. And I think that they are really trying to take a look at vitamin therapy, take a look at pesticides and other kinds of trials, genetics.

They have made some progress in cancer research, but at least correct the sexism, correct the biases, let them change their minds about these guidelines and admit they made a mistake and go forward, but give them the tools and the resources.

And I know you don't have a lot of money to work with. Take it out of the military research and give them some of that money. And my goodness, they'll go to town. They've got some brilliant people there, and I think that they want to do a good job.

Ms. SNOWE. Mr. Sanders, I think one of the good things that has come out of our efforts in the last few years is the fact that the National Institutes of Health did establish a women's health initiative that will include 160,000 women nationwide in a clinical study trial, to talk about the interrelationship between diet and hormone replacement, all of the questions that have not been answered in terms of the impact on breast cancer, ovarian cancer, and so on.

These have been unanswered questions for generations, which is regrettable, which also, I think, underscores the fact that they still remain unanswered.

What I found, again ironic, a few months ago, the National Advisory Committee indicated that this women's health initiative was just far too expensive, that we shouldn't devote this much in the way of resources to funding this nationwide research that, once and for all, would answer those questions.

And on a personal note, my mother died from breast cancer in 1955, and I can't tell you that those statistics have improved since that time, when, in fact, they haven't—one in eight. And I think that that's a sad commentary about where we stand today.

So to answer your question, no, we have not done enough. We haven't been innovative. In some ways, I think we've regressed.

Mr. TOWNS. The gentleman's time has expired. At this time I yield to Congressman Mica.

Mr. MICA. Thank you, Mr. Chairman.

Well, I've looked at some of the information and testimony that's before us today, and I guess part of the purpose of this hearing, is to crucify the National Cancer Institute's revision of its mammography guidelines.

I'm not sure if I'm prepared to do that, based on the conflicting scientific testimony that's before us. I imagine that they didn't just publish this based on some whim, but based on studies. And I notice, that we have conflicting testimony before us today.

One of these items that conflicts with some of the other testimony in favor of keeping similar guidelines or stronger guidelines is by Dr. Smart, and he says the largest study of screening women age 40 to 49, 93,471 cases, comes from the breast cancer detection demonstration program. And then further on, he says the number of women screened annually yields slightly over two breast cancers per thousand women, regardless of age. Those are just some of the statistics from the study.

So when you have split scientific data, and you're faced with limited resources, what do you do?

Ms. SLAUGHTER. We err on the side of women.

Mr. MICA. But again, and I think some of what Ms. Oakar had stated, that you need to look at the preventative side, and you try to see what the cost benefit is scheduled further out.

And certainly, it seems like it is rather important, but you know, serving as a Member of Congress, which all of you on the panel have served or currently serve, you look at some of the statistics, estimated new cancer cases by State, and you have U.S. breast cancer, 182,000. Then you move over to prostate cancer is 200,000.

What if, you know, I come in with a panel of male members and say that, there's not enough attention to this?

Mrs. SCHROEDER. That was my point, Congressman Mica. Nobody's touched it.

Ms. SLAUGHTER. But I should tell you, we didn't want to micromanage research. I know you can't. We had to do something to catch up.

But you would be interested to know that in all those things that really affect women, we included prostate cancer in the budget.

Mr. MICA. Well, we can't turn this into a war of the sexes, but I have to also——

Ms. SLAUGHTER. But it has been.

Mr. MICA. I know, but it shouldn't be. And——

Ms. SLAUGHTER. No, it shouldn't.

Mr. MICA [continuing]. My point here, too, is I think that Representative Sanders makes a very good point. Back when I served in the Florida legislature, I looked at this problem because we have a high incidence of cancer in Florida. And I authored the Cancer Registry and Research Act back in 1979 because I found out then that you don't have basic information. And that's what we lack in the country.

So wouldn't it be better if we utilized our resources and our efforts to get the basic information, so that we can tell if there are hereditary causes or environmental things that are causing these——

Ms. SLAUGHTER. There are probably a number of causes.

Mrs. SCHROEDER. Why is it either/or?

Mr. MICA. I think you have to take this in an order—no, I think if you look at cancer, too, here, I mean, we all have colons and rectums and lungs and skin and pancreas and leukemia. Cancer doesn't know sexes, in my estimation.

So shouldn't we concentrate on basic research, and then also finding out the basic information that helps us? And see, the people who come here with the loudest voice and the loudest petition to Congress, with AIDS, we're directing science all over the ballpark and we're not accomplishing the basic research mission and getting the basic information.

Ms. SNOWE. But the whole issue is here that this hasn't been done on conclusive studies. I mean, the fact of the matter is that clinical trials that have been done do not include a significant number of women. It has not been age-specific to this group, 40 to 49. You're going to be hearing from witnesses today——

Mr. MICA. Mr. Smart's study is not valid, with 93,000 women between ages 40 and 49?

Ms. SNOWE. You will hear testimony from witnesses here today that will suggest otherwise, that it's more than a marginal trend when you have five of the eight randomized trials that showed a 17 percent reduction in death among women in this age category. And you'll be hearing from Dr. Kopans, and I think that it's very important.

So why wouldn't we want to err on the side of prudence in a life-saving matter? It's not a matter of sexes here.

Mr. MICA. I have no problem with that.

Ms. SNOWE. It is a matter of life and death, and because it's not conclusive, there are strong differences of opinion. But the fact is, as you—Dr. Sickles and Dr. Kopans who are affiliated with the University of California Medicine, San Francisco, and Dr. Kopans with the Harvard Medical School and Mass General will tell you, as well as 22 national organizations, including the American Cancer Society, that they don't agree with the rescinding of these guidelines. So I think that tells us something.

Mr. MICA. Well, again, we do have conflicting scientific testimony before us, and you have—NCI has gone in one direction.

What I'm saying is wouldn't it be much more productive? I would love to do everything for everyone. And I can cite examples of cancer that will bring tears to everyone's eyes here. But don't you think it's important, rather than running the Congress—the Congress running the agencies and everyone in all these different directions, that we focus and concentrate on one, getting the information and scientific data that we need, and then two, conducting the basic research that can give us hopefully a cure for all kinds of cancer?

Mrs. SCHROEDER. Congressman Mica, please let the caucus send to your office information about our 10 years of trying to get equal research on this issue.

Mr. MICA. Well, now I understand——

Mrs. SCHROEDER. And we have been shut out.

Mr. MICA. It's my understanding that we're spending even more in the breast cancer area than we are in the prostate.

Mrs. SCHROEDER. But we haven't been spending it for a long time. Let me take on your prostate example, too. There aren't any hearings going on talking about how many PSA's men can have to detect prostate cancer. And there's also no hard data about the effectiveness of PSA's, but we absolutely know—no one would question that. They're saying, "My goodness, if they save lives, if they detect even a small percentage of cancer, let's push for them."

And I suggest you would do the same for women.

Mr. MICA. But 200,000 instances——

Mrs. SCHROEDER. How old are——

Mr. MICA. 182,000 breast cancer versus 200,000, using that logic, then we should have more research and money going into prostate cancer, which I understand Senator Dole is now on his particular——

Ms. SLAUGHTER. We're not arguing that we should spend——

Mr. MICA. Again, my question is wouldn't we be much better off in focusing on what Mr. Sanders said, that we deal with basic information that we lack about the problem, and getting the science, and then also on research to find a cure across the board?

Ms. SLAUGHTER. But you're not finding a cure for diphtheria here. There are many causes of cancer. There are many different types of cancer. You're not going to find one single answer. And without any question, there has to be——

Mrs. SCHROEDER. And Congressman Mica, I wish you could see this thing over here. It says that cancer screening can protect the lives of 13,500 women between the ages of 40 and 49. We have that data.

Mr. MICA. And if we cross that out and put "men" there, we could do the same thing.

Ms. SLAUGHTER. But we're not arguing with that.

Mrs. SCHROEDER. But we're not taking away from that. No one's arguing that.

Ms. OAKAR. Congressman, just as we advocate blood tests for prostate cancer. The message is the problem. The message is wrong. What do women and their families want? I think they want——

Mr. MICA. Well, I would agree with you that maybe they've sent a wrong message because even the study does say that regardless—and everyone should know that—regardless of the age group, according to at least this study, you have an equal chance in every age group of——

Ms. SLAUGHTER. But we're not arguing——

Mr. MICA. And you brought that out very eloquently with your——

Mr. SANDERS. Would the gentleman yield for a brief moment?

Mr. MICA. I yield to the gentleman from——

Mr. SANDERS. Thank you. Let's not see this discussion degenerate into prostate cancer versus breast cancer.

Mrs. SCHROEDER. That's right.

Mr. SANDERS. More, the issue I think that we all agree on, as Mr. Mica correctly pointed out, that we need basic and fundamental broad research as to the causes of cancer.

The way I see it, and Mr. Mica makes a point and says there's a difference of opinion here. The issue is who should ultimately have the freedom to make that choice? And I think it's got to be the woman herself. And I think what we're talking about is making sure that people have the coverage to make that option.

Now, if a woman has the coverage, she reads evidence and she says, "I think I don't want to do this mammogram." No one here is forcing her to do that; is that correct?

Mrs. SCHROEDER. Yes.

Mr. SANDERS. What we are saying is that she should make that decision, and it should not be influenced by financial disincentives, if you like. I mean, is that a correct assumption?

Ms. SLAUGHTER. That's right.

Mrs. SCHROEDER. Or a politician.

Mr. SANDERS. That's right.

Ms. SNOWE. Can I make a point here? I'd like to make a point because I don't think that we're here to leave the impression that we ought to spend more money on breast cancer than prostate cancer. I hope we can spend more money on both, in all, because I don't think we've done enough in the cancer arena.

But it does disturb me when the NCI issues their guidelines and it says now, "NCI recommends women discuss with a health professional the advisability of breast cancer screening with mammography, taking into account family history of breast cancer and other risk factors."

Do you know how confusing that all is? As one who's in a high risk category myself, I've been confused for the better part of the decade. Every year or every other year, in my category? But I've decided to be more prudent—every year.

But to say now, "We'll leave it up to women to discuss with a health professional," when, in fact, most doctors—many doctors, I should say, do not recommend a mammogram. It's a woman that says to the doctor, "I want a mammogram."

But to leave the entire burden as to whether it might be all right——

Ms. OAKAR. Can I say something about that study that you keep referring to? That study provided the impetus for the new NCI policy. The study did not include a statistically significant number of women. The lead investigator admitted that the equipment used was substandard, even for its time, in the 1980's. The study was not carried out for a long enough period of time.

The study inappropriately included women with advanced stage breast cancer, and approximately 25 percent of the control group, supposedly not screened, later admitted that they were screened during the test period.

And then, when they had two panels at the NCI workshop, and this is all in my statement, but it's important to say this, I think, publicly, one panel said, "We ought to change the guidelines;" the second panel said, "We ought not to do this," and they took the first panel's recommendation.

Now, what do women want? They want you to know that breast cancer is an epidemic. They want to have informed decision. They want to have early detection and prevention. And yes, they want more research dollars to find a cure. It's that simple. And that should be the same for prostate cancer and any other disease.

Mr. MICA. If I might, Mr. Chairman, if you would yield just a few seconds to sort of close. I think we're all trying to get to the same point, which is more money, research for all types of cancer, and hopefully a cure, more information.

I think this panel is good because we sort of worked around the fringes of the larger question, which is the question before the Congress now, and that is health care, and how we formulate health care for the people of this country.

And I think that anything that we do needs to have an element that looks at prevention and preventative care because, as you've pointed out, how worthwhile it can be, whether it's for breast cancer, prostate cancer, whatever.

Ms. SLAUGHTER. Childhood disease.

Mr. MICA. The earlier you find it the better. Unlike many of the problems we've developed in the past where we waited till it got really bad, so I admire your work in getting Medicare coverage. But I think that that's part of the larger question that we need to address, and that when we look at the preventative mode in health care, we address those things.

But again, I look forward to working with you on both research, and then also getting the information and data that we need to resolve and address all types of cancer. Thank you.

Mr. TOWNS. We thank the members of the—sorry, we've just been joined by another member of the subcommittee.

Mr. BARRETT. Keep up the good work.

Mr. TOWNS. We thank all of you for your testimony. We look forward to working with you.

Mrs. SCHROEDER. We hope we live long enough to see it happen. There have been days when we wonder. Thank you, Mr. Chairman. You were wonderful.

Mr. TOWNS. Thank you.

At this time I call on the second panel. Carolyn Brown-Davis, please come forward. Louanner Peters, Theora Dodd, please come forward.

Since this is an investigatory subcommittee hearing, I'm going to ask all of you to swear or affirm an oath.

[Witnesses sworn.]

Mr. TOWNS. Let the record reflect that the witnesses have answered in the affirmative. Before we begin, I would like to reiterate the subcommittee's appreciation for your willingness to testify on such a personal and sensitive matter. We really appreciate it very, very much.

As you know, the subcommittee's rules are that you have 5 minutes to speak and your entire statement will be included in the record. Please begin by summarizing your written testimony, within the 5-minute period. The members will raise questions with you after your testimony.

Why don't you start Mrs. Brown-Davis.

STATEMENT OF CAROLYN BROWN-DAVIS, BREAST CANCER SURVIVOR

Mrs. BROWN-DAVIS. Good morning, Mr. Chairman and members of the subcommittee. I want to thank you, Representative Towns and the Subcommittee on Human Resources and Intergovernmental Relations, for holding this very important hearing on the issue of breast cancer.

My name is Carolyn Brown-Davis and I'm very happy to be here with you today to speak as a survivor of breast cancer. My story begins in a rather ordinary manner. Born and educated in the Midwest, having traveled extensively and lived in several cities around the U.S.A., I arrived in Washington, DC through a series of memorable events, as did many of us here today.

In July 1992, I had my first mammogram. The reason I did was because my gynecologist, Dr. Caryl Mussenden, recommended that I get a baseline. There was no problem. The breast exam revealed a fibrocystic condition, as usual. It had always been this way. Dr. Mussenden recommended that I get a mammogram when she last examined me, but lacking the financial means or insurance, I did not.

This year was different. I took her recommendation and made an appointment. My mammogram report was requested by my family physician, Dr. Rodney Ellis, as I sat in his office. We were told that the mammogram should be repeated in 6 months.

I remember asking what that meant. Dr. Ellis told me that we should proceed cautiously, but not to worry. We agreed that the mammogram would be repeated in the spring of 1993, and that I was to report any change in my breast.

Obviously, in order to report any change, I was going to take the breast self-exam more seriously than I had in the past. So a routine was established. I assure you, of the women with whom I have spoken, many have no routine for conducting self-breast exams, and those who do often do not discover a perceptible change in the mass of their breast.

Within 6 months, I felt a new mass in my right breast, which felt unlike any other I had felt before. I find it quite interesting that a number of women with whom I have spoken have never experienced a change, yet were diagnosed with breast cancer from a mammogram.

Within a week, the existence of this new mass had been confirmed by Dr. Ellis and he immediately referred me to Dr. Lasalle Lefall, chief of surgery at Howard University Hospital and past president of the American Cancer Society. Dr. Lefall determined, through an aspiration biopsy, that the mass was not a cyst but a tumor, which had to be removed immediately. Surgery was performed and the tumor was found to be malignant.

I was given a choice of having a lumpectomy or a mastectomy—a choice because, in my case, the results would be the same. At this point, I should mention to you that I was beginning to understand that I had breast cancer. Me, a youthful 40 something, newly married, a volunteer health caretaker, very involved in a family business, and with no history of cancer on either side of my family, had cancer. Carolyn Brown-Davis, a nonsmoker who exercised faith-

fully, ate properly, had gynecological exams on time, had cancer. What did this mean? How was my life going to change?

I was confused and frightened and sought the advice of reported experts on breast cancer. Dr. Lefall referred me to the American Cancer Society, where the resident clinical social worker, Wilma Schuren, invited me to visit her offices to review literature and videos which she thought would help me better understand this disease and put my fears to rest.

My sister, who lives in St. Louis, spoke with colleagues and found out about Zora Brown, president of the Breast Cancer Resource Committee, and referred me to her. I decided not to tell my parents yet because cancer had always been discussed in subdued tones when growing up in our home, and always meant the person had a short time to live.

I decided on the lumpectomy. Surgery was scheduled. Twenty lymph nodes were removed and dissected. There was no further malignancy found in the lymph nodes, and other scans of lungs, liver, spleen, and bone were clean. I underwent 6 weeks of radiation therapy, the cumulative effects of which left me facing a long period of recovery. It is now 10 months after my surgery, and I have recovered and returned to my full schedule.

In many ways I am happier and now more appreciative of life than I ever was before. Since becoming a member of the club—I assure you most women, given the choice, would rather not hold membership—I've learned that most African American women are diagnosed at a much later stage in the development of a disease than I was. I have learned that African American women experience a higher incidence of death from breast cancer. But what frightens me most is that no one can predict who will be joining the club. The only answer is early diagnosis.

Additionally, the costs associated with the care of this disease tend to escalate when detection occurs in the advanced stages. That's a cost measured in terms of emotional and financial well-being, and one's life. And so, ladies and gentlemen, I am quite happy that my first mammogram was done before the age of 50. Were it not, I might not be talking to you today, but I am, and I have a future to which I look forward.

I'd like to introduce you to some of my fellow club members who were diagnosed with breast cancer from a mammogram before age 50. They're here today with me. Marsha Braxton and Clara Pate. We think a main part of the national strategy for treatment of breast cancer should focus on making it possible for all women to gain access to mammograms prior to age 50, so we implore the members of the subcommittee to assist in the enactment of such a policy into the national strategy.

The rapid increase in numbers of women diagnosed with breast cancer are truly frightening. We must intervene to stop this deadly epidemic. We need your help. Again, thank you for this opportunity to testify.

[The prepared statement of Mrs. Brown-Davis follows:]

A TESTIMONY

TO THE

US HOUSE OF REPRESENTATIVES
HUMAN RESOURCES &
INTERGOVERNMENTAL RELATIONS
SUBCOMMITTEE

PRESENTED BY

CAROLYN BROWN-DAVIS

A BREAST CANCER SURVIVOR

MARCH 8, 1994

GOOD MORNING, MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE. I WANT TO THANK YOU, REPRESENTATIVE TOWNS, AND THE SUBCOMMITTEE ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS, FOR HOLDING THIS VERY IMPORTANT HEARING ON THE ISSUE OF BREAST CANCER.

MY NAME IS CAROLYN BROWN-DAVIS, AND I AM VERY HAPPY TO BE HERE WITH YOU TODAY TO SPEAK AS A SURVIVOR OF BREAST CANCER. MY STORY BEGINS IN A RATHER ORDINARY MANNER. BORN AND EDUCATED IN THE MIDWEST, HAVING TRAVELED EXTENSIVELY AND LIVED IN SEVERAL CITIES AROUND THE USA, I ARRIVED IN WASHINGTON, DC THROUGH A SERIES OF MEMORABLE EVENTS, AS DID MANY OF US HERE TODAY.

IN JULY OF 1992, I HAD MY FIRST MAMMOGRAM. THE REASON I DID WAS BECAUSE MY GYNECOLOGIST, DR. CARYL MUSSENDEN, RECOMMENDED THAT I GET A BASELINE. THERE WAS NO PROBLEM. THE BREAST EXAM REVEALED A FIBROCYSTIC CONDITION, AS USUAL. IT HAD ALWAYS BEEN THIS WAY. DR. MUSSENDEN RECOMMENDED THAT I GET A MAMMAGRAM WHEN SHE LAST EXAMINED ME. BUT LACKING THE FINANCIAL

MEANS OR INSURANCE, I DID NOT. THIS YEAR WAS DIFFERENT. I TOOK HER RECOMMENDATION AND MADE AN APPOINTMENT.

MY MAMMOGRAM REPORT WAS REQUESTED BY MY FAMILY PHYSICIAN, DR. RODNEY L. ELLIS, AS I SAT IN HIS OFFICE. WE WERE TOLD THAT THE MAMMOGRAM SHOULD BE REPEATED IN SIX MONTHS. I REMEMBER ASKING WHAT THAT MEANT. DR. ELLIS TOLD ME IT MEANT WE SHOULD PROCEED CAUTIOUSLY, BUT NOT TO WORRY. WE AGREED THAT THE MAMMOGRAM WOULD BE REPEATED IN THE SPRING OF 1993, AND THAT I WAS TO REPORT ANY CHANGE IN MY BREASTS. OBVIOUSLY, IN ORDER TO REPORT ANY CHANGE, I WAS GOING TO TAKE THE BREAST SELF EXAM MORE SERIOUSLY THAN I HAD IN THE PAST. SO, A ROUTINE WAS ESTABLISHED. I ASSURE YOU, OF THE WOMEN WITH WHOM I HAVE SPOKEN, MANY HAVE NO ROUTINE FOR CONDUCTING SELF BREAST EXAMS. AND, THOSE WHO DO OFTEN DO NOT DISCOVER A PERCEPTIBLE CHANGE IN THE MASS OF THEIR BREASTS.

WITHIN SIX MONTH, I DISCOVERED A NEW MASS IN MY RIGHT

3.

BREAST, WHICH FELT UNLIKE ANY OTHER I HAD FELT BEFORE. I FIND IT QUITE INTERESTING THAT A NUMBER OF WOMEN WITH WHOM I HAVE SPOKEN HAVE NEVER EXPERIENCED A CHANGE, YET WERE DIAGNOSED WITH BREAST CANCER FROM A MAMMAGRAM.

WITHIN A WEEK, THE EXISTENCE OF THIS NEW MASS HAD BEEN CONFIRMED BY DR. ELLIS, AND HE IMMEDIATELY REFERRED ME TO DR. LASALLE LEFALL, CHIEF OF SURGERY AT HOWARD UNIVERSITY HOSPITAL, AND PAST PRESIDENT OF THE AMERICAN CANCER SOCIETY. DR. LEFALL DETERMINED THROUGH AN ASPIRATION BIOPSY THAT THE MASS WAS NOT A CYST, BUT A TUMOR WHICH HAD TO BE REMOVED IMMEDIATELY. SURGERY WAS PERFORMED AND THE TUMOR WAS FOUND TO BE MALIGNANT. I WAS GIVEN A CHOICE OF HAVING A LUMPECTOMY OR MASTECTOMY--A CHOICE BECAUSE, IN MY CASE THE RESULTS WOULD BE THE SAME. AT THIS POINT I SHOULD MENTION TO YOU THAT I WAS BEGINNING TO UNDERSTAND THAT I HAD BREAST CANCER. ME, A YOUTHFUL

4.

FORTY SOMETHING, NEWLY MARRIED, A VOLUNTEER HEALTH CARETAKER, VERY INVOLVED IN A FAMILY BUSINESS, AND WITH NO HISTORY OF CANCER ON EITHER SIDE OF MY FAMILY, HAD CANCER. CAROLYN BROWN-DAVIS, A NON-SMOKER WHO EXERCISED FAITHFULLY, ATE PROPERLY, HAD GYNECOLOGICAL EXAMS ON TIME, HAD CANCER. WHAT DID THIS MEAN? HOW WAS MY LIFE GOING TO CHANGE?

I WAS CONFUSED AND FRIGHTENED, AND SOUGHT THE ADVICE OF REPORTED EXPERTS ON BREAST CANCER. DR. LEFALL REFERRED ME TO THE AMERICAN CANCER SOCIETY WHERE THE RESIDENT CLINICAL SOCIAL WORKER, WILMA SCHUREN, INVITED ME TO VISIT HER OFFICES TO REVIEW LITERATURE AND VIDEOS WHICH SHE THOUGHT WOULD HELP ME BETTER UNDERSTAND THIS DISEASE AND PUT MY FEARS TO REST. MY SISTER, WHO LIVES IN ST. LOUIS, SPOKE WITH COLLEAGUES AND FOUND OUT ABOUT ZORA BROWN, PRESIDENT OF THE BREAST CANCER RESOURCE COMMITTEE, AND REFERRED ME TO HER. I DECIDED NOT TO TELL MY PARENTS YET BECAUSE CANCER HAD ALWAYS BEEN

5.

DISCUSSED IN SUBDUED TONES WHEN GROWING UP IN OUR HOME, AND ALWAYS MEANT THE PERSON HAD A SHORT TIME TO LIVE.

I DECIDED ON THE LUMPECTOMY. SURGERY WAS SCHEDULED. TWENTY (20) LYMPH NODES WERE REMOVED AND DISSECTED. THERE WAS NO FURTHER MALIGNANCY FOUND IN THE LYMPH NODES, AND OTHER SCANS OF LUNGS, LIVER, SPLEEN AND BONE WERE ALSO CLEAN. I UNDERWENT SIX WEEKS OF RADIATION THERAPY, THE CUMULATIVE EFFECTS OF WHICH LEFT ME FACING A LONG PERIOD OF RECOVERY. IT IS NOW TEN MONTHS AFTER MY SURGERY AND I HAVE RECOVERED AND RETURNED TO MY FULL SCHEDULE.

IN MANY WAYS I AM HAPPIER, AND NOW MORE APPRECIATIVE OF LIFE THAN I EVER WAS BEFORE. SINCE BECOMING A MEMBER OF "THE CLUB,"--I ASSURE YOU MOST WOMEN GIVEN THE CHOICE WOULD RATHER NOT HOLD MEMBERSHIP-- I'VE LEARNED THAT MOST AFRICAN AMERICAN WOMEN ARE DIAGNOSED AT A MUCH LATER STAGE IN THE DEVELOPMENT OF THE DISEASE THAN I WAS. I HAVE LEARNED THAT AFRICAN AMERICAN WOMEN

6.

EXPERIENCE A HIGHER INCIDENCE OF DEATH FROM BREAST CANCER. BUT, WHAT FRIGHTENS ME MOST IS THAT NO ONE CAN PREDICT WHO WILL BE JOINING "THE CLUB." THE ONLY ANSWER IS EARLY DIAGNOSIS.

ADDITIONALLY, THE COSTS ASSOCIATED WITH THE CARE OF THIS DISEASE TEND TO ESCALATE WHEN DETECTION OCCURS IN THE ADVANCED STAGES. THAT'S A COST MEASURED IN TERMS OF EMOTIONAL AND FINANCIAL WELL BEING, AND ONE'S LIFE!

AND SO, LADIES AND GENTLEMEN, I AM QUITE HAPPY THAT MY FIRST MAMMAGRAM WAS DONE BEFORE THE AGE OF 50. WERE IT NOT I MIGHT NOT BE TALKING TO YOU TODAY. BUT, I AM, AND I HAVE A FUTURE TO WHICH TO LOOK FORWARD.

I'D LIKE TO INTRODUCE YOU TO SOME OF MY FELLOW CLUB MEMBERS WHO WERE DIAGNOSED WITH BREAST CANCER FROM A MAMMAGRAM BEFORE AGE 50.

WE THINK A MAIN PART OF THE NATIONAL STRATEGY FOR TREATMENT OF BREAST CANCER SHOULD FOCUS ON MAKING IT

POSSIBLE FOR ALL WOMEN TO GAIN ACCESS TO MAMMOGRAMS PRIOR TO AGE 50. SO WE IMPLORE THE MEMBERS OF THE COMMITTEE TO ASSIST IN THE ENACTMENT OF SUCH A POLICY INTO THE NATIONAL STRATEGY.

THE RAPID INCREASING NUMBERS OF WOMEN DIAGNOSED WITH BREAST CANCER ARE TRULY FRIGHTENING. WE MUST INTERVENE TO STOP THIS DEADLY EPIDEMIC. WE NEED YOUR HELP!

AGAIN, THANK YOU FOR THIS OPPORTUNITY TO TESTIFY.

Mr. TOWNS. Thank you for your testimony. Ms. Peters.

STATEMENT OF LOUANNER PETERS, CONSULTANT, HENDERSON PETERS GROUP

Ms. PETERS. Thank you. Mr. Chairman, subcommittee members, I really appreciate this opportunity to share with you some of my thoughts on this. But first, Mr. Chairman, I would like to thank you for the resolution you sponsored because I think it's very important that the overall threshold, across the board, be at age 40 for annual mammogram, and for high risk groups—this being a very significant component of the resolution, high risk groups.

And I truly believe that African American women fall into that high risk group, as a whole almost, because if we look at even NCI statistics, it shows that between the ages of 40 and 44, African American women are diagnosed 2 percent more than white women, with breast cancer, but we die 54 percent more. That's our mortality rate. In the ages between 25 and 39, we are diagnosed 15 percent more than white women, but our death rate is 102 percent more in that age group. So even at 40, it does not catch us. The disease reaches us at a much younger age and much, much more aggressively.

So NCI's new or revised guidelines are ludicrous. We're faced with a reality, not just from the sexism of science, research, and treatment in America, from racism also. Just in the process by which we gain information, the public information campaign on breast cancer, in the main, has suggested far too often to African American women that it is a white woman's disease. It is not something we should be concerned about. It is something we can put on the back burner. That is not the case. But the information, and the images that we get, the tone for what we set as a priority in our lives. So that tone has, in a sense, been set by agencies like the National Cancer Institute. To now set a guideline for annual mammograms to begin at 50 is placing a large group of people almost in double jeopardy. We cannot have that in America.

At 39, I was diagnosed with breast cancer. Luckily, I'd had my baseline mammogram at 36. Because of that baseline, my physicians were able to look at the results and say, "This is not something we should wait on. We need to move rapidly and decisively."

Within 10 days of comparing the mammograms, I was on the operating table. First time, just to remove the lump, but it was so advanced in its invasive nature that I was hospitalized within 7 days for a modified radical mastectomy. That was 6 years and 1 week ago yesterday. Within 1 week after that, I was back for a mastectomy on the other side.

So I'd almost waited too late. I was in the later stages of stage II breast cancer. I'm an only mom, an only parent, rather, for a 13 year old. My son was eight at the time. I'm very happy that he does not have to face this world without his only parent.

We can't afford to remove any diagnostic tool in this war on breast cancer. It is too severe, too critical, and too drastic, particularly for African American women. We must say to NCI, "You cannot, cannot establish 50 as the threshold. It is deadly to do so."

I would like to include all of my notes.

[The prepared statement of Ms. Peters follows:]

TESTIMONY OF MS. LOUANNER PETERS
CONSULTANT, HENDERSON PETERS GROUP
AND FORMER CHIEF-OF-STAFF FOR U.S. REP GUS SAVAGE
BEFORE THE SUBCOMMITTEE ON
HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS
MARCH 8, 1994

Mr. Chairman and Members of the Subcommittee:

First, I'd like to commend you, Mr. Chairman, for your sensitivity in sponsoring the resolution which calls for lower age thresholds for annual mammogram examinations. I'd also like to thank the committee for giving me the opportunity to appear before you today on this urgent and critical topic.

Breast cancer is a horrifying disease, Mr. Chairman. When it's not fatal, it leaves women scarred, both emotionally and physically. As a breast cancer survivor, I can attest to this pain first-hand. Consequently, I was very distressed to learn of the National Cancer Institute's decision to revise its mammography guidelines and establish 50 as the threshold for annual mammograms. With over one-third of all breast cancer deaths occurring before the age of 50, such a move, once it permeates federal and private health care policies, will leave women across this country vulnerable to the ravages of this disease; and I'm here to tell you that a large percentage of these women (under 50) are African Americans -- women for whom the safety net against breast cancer already has a large, gaping hole.

Mr. Chairman, not only are African American women far more likely than white women to die of breast cancer at any age, once they have it, but they are also far more likely than white women to contract it before age 50. An NCI study bears this out. It shows that, between the ages of 40 and 44, African American women are 2% more likely than white women to get the disease and 54% more likely to die from it. The disparity grows drastically in the younger age brackets. Between 25 and 39, for example, African American women are 15% more likely to get the disease and 102% more likely to die from it.

While there are many solid reasons for this disparity, Mr. Chairman, the one most relevant to this forum concerns a pattern of miseducation about breast cancer, as it relates to African Americans. Viewed through the eyes of a thirty-something African American female, breast cancer is someone else's problem; and unless NCI corrects its revised guidelines, it will surely reinforce such beliefs.

Mass media, public ad campaigns, and television documentaries reinforce the notion for African American women that breast cancer is someone else's problem. For example, with only the rarest of exceptions, the stories of pain and suffering are told by white faces on television. To African American women, the

presentation creates the impression that breast cancer is a white woman~s disease, in the main.

NCI's revised guidelines will exacerbate this alienation even further, but on the basis of age as well as race. Just as the media campaigns are virtually all geared towards white women, the NCI recommendations will send a message to women under 50 that breast cancer is a disease not to be taken seriously. If NCI stays with this revised position that women under 50 don't need annual mammograms, and if such a position becomes the basis for national policy and medical insurance policies, then the women who statistically need mammograms the most -- thirty-something African American women and forty-something women in the general population -- will be less likely to have them done.

Mr. Chairman, I am an African American breast cancer survivor. I was diagnosed at 39 years of age at Stage II. In fact, yesterday marked the Sixth Anniversary of my second mastectomy, which followed my first mastectomy by only one week. I am the single mother of a thirteen year old; and I know that, if it wasn't for the role that mammography played in my diagnosis, there is a good chance that I might not have been there for him. I -- like many other women in this room today -- am living proof that the NCI proposal is deficient; and I can only hope that your resolution prevails. Under your resolution, which calls for annual mammograms for women as young as thirty-five, if they are in high-risk groups.

(Introduce survivors in the audience.)

Mr. Chairman, with, African American women, between 25 and 39, 15% more likely to get the disease and 102% more likely to die from it, we cannot afford to have any cutbacks in our use of mammograms as a diagnostic tool in the fight against breast cancer.

Mr. TOWNS. Without objection, your entire statement will be included in the record. Thank you for your testimony. Ms. Dodd.

STATEMENT OF THEORA EVANS DODD

Ms. DODD. Good morning. I would especially like to thank Congressman Towns for affording me this opportunity to speak with you this morning. I am also providing extensive written comments for the record.

My daughter Kimberly Toirelle Dodd, completed her undergraduate course work at Howard University in December 1991. She was diagnosed with stage IV breast cancer on April 9, 1992. She was 23 years old. She died 11 months later. The disease metastasized to her bones, bone marrow, liver, and possibly her ovaries.

During that timeframe, she underwent high-dose chemotherapy, surgury, an autologous bone marrow transplant, and radiotherapy. Her treatment protocol was managed by two premier facilities—Duke University Medical Center and the University of Iowa Hospitals and Clinics. They consulted with other institutions around the country.

Kimberly did not fit the model for breast cancer that is so widely purported. No other female in our family has ever been diagnosed with the disease. Her maternal great-grandmother died at the age of 92, two grandmothers are alive and well in their sixties and seventies, and to date, neither I nor her sister have been physically impacted by this disease.

But her outcome was no different than that of many other young women. It was fatal. It became very apparent early in the treatment process that her physicians were working with an aberrant case. Reportedly, she was the youngest case diagnosed and treated at either institution. They could neither discern the nature, the structure, or the extent of her condition.

It would seem that one can not treat what one does not understand. The medical personnel at both institutions were caring and nurturing individuals, but they attended to only one aspect of her being—the physical component. They did not address or recommend resources for working through the tremendous psychological impact this disease had on her or our family.

The following statement was echoed by both her surgeon and her oncologist upon diagnosis—"A positive psychological response will be a key indicator for a successful treatment outcome." Resiliency, you see, is the one variable that the medical profession has identified as a primary factor in the treatment process. Yet neither mental health assessment nor services is a component of the protocol. The psychological impact was observed, but not directly addressed or anticipated by physician ordered intervention. The term "psychosocial" describes aspects of development which are both psychological and social in nature.

By way of an example, allow me to share a couple of anecdotes with you. Once Kim became bedridden, with intense pain and general weakness, it took from 45 minutes to 1 hour for us to move her from her bed to a portable commode, which was less than 2 feet away, and back again. This activity was demeaning and humiliating for her. She said to me on one occasion, "I'll never walk to the bathroom again. That's difficult to grasp."

Subsequently, there came a point when I had to feed her. She could no longer raise utensils to her mouth. She said, "Did you ever think that you would have to care for me as if I were a baby again?" These are psychosocial constructs, issues of autonomy, independence, and intimacy.

Women are neither offered formal or informal emotional support once a breast cancer diagnosis is given. This disease and its treatment diminishes a woman's self-esteem and it can impair one's capacity to seek out and maintain intimacy with significant others.

I personally sought the services of social workers in both Iowa City, IA and Durham, NC to facilitate my daughter's emotional stability. Please note that my concerns regarding these issues are for all women, but my focus is on women of African descent. Young women of African descent need to be made aware of the impact breast cancer can have on them. It is a fact that they have neither been targeted for the dissemination of public service announcements [PSA's], nor have health education materials been distributed to this population warning them of the risks, and offering them preventative and primary care.

In general, we have been lead to believe that breast cancer is basically a "white woman's" disease. The model that is so widely proclaimed, postmenopausal women 50 years of age and over, zero parity and family histories of disease, may not apply to all of us.

The indicators may, in fact, be very different. Across age cohorts, we know that the outcomes, percentagewise, are generally not favorable for women of color. As highlighted in the conference sponsored by the National Cancer Institute, the Office of Research in Women's Health, and the National Institute for Child Health and Human Development, "Breast Cancer in Young Women, Strategies for Future Research," January 28, 1993, African American women are diagnosed at an earlier age and in greater proportion than their Euro-American counterparts. Furthermore, the disease is usually a death sentence for this population. Mortality rates are high. Generally, young women do not access the health care system early in the disease process. Additionally, physicians misdiagnose, feeling that the patient does not fit the model, thereby delaying treatment further and compromising the outcome further.

And, most importantly because of their age, cell division is very rapid, spread of the disease happens quickly, and vital organs are compromised. Likewise, it also becomes life-threatening.

The significance of a breast self-examination and baseline mammography means absolutely nothing to a female in her twenties. These young women perceive themselves as invincible. It is therefore incumbent upon us to educate them.

I am here to challenge NCI to incorporate the assessment of psychosocial factors in young women with life-threatening stages of breast cancer. I want the diagnostic protocols to include measures of resilience and the provision of mental health services, as needed thereafter. Second, I propose that funds be earmarked for innovative research grants to identify mechanisms for early diagnosis that offer enhanced specificity and sensitivity. And lastly, research is needed to secure alternative treatment options that are less toxic. Certainly, a cure would be an optimal sequela to this research.

I do not support the utilitarian model that has led to the current guidelines implemented by NCI, raising the suggested age for a mammogram baseline. We, meaning the citizens of this United States, cannot afford to knowingly dispose of a few for the benefit of the greater number.

For too long, women's health care has been neglected. Now that it is in vogue to examine gender differences, let us not falter by failing to address ethnic variances also. Thank you.

[The prepared statement of Ms. Dodd follows:]

Good morning!

I would like to thank all of you for giving me this opportunity to share the experiences of my daughter, Kimberly Toirelle Dodd, her sister, Karetha Anita Dodd and significant others (family, friends and health providers). Let me be very clear - it is too late for my child, she was a beautiful, intelligent and energetic young woman. But I am here to plead a case for all women and specifically for young african-american women who may be at-risk for breast cancer.

Kimberly had completed her undergraduate studies at Howard University and was residing in Chicago. She telephoned me and related that she had found a lump in her breast. She initially sought medical services from a women's clinic and was referred to a major health care facility in that locale. I subsequently made an appointment for her in Iowa City; she came home to receive care. Prior to examining her the surgeon said, "no history of major illness, no long-term medication use, don't worry, it's nothing, aspiration should be sufficient". The assessment was reversed within ninety (90) minutes. He clearly and succinctly stated that the difference in her health outcome was emotional stability.

We searched medical libraries for research. We sought data that would guide us in terms of treatment options and expected outcomes. We found medical studies with few subjects and inconclusive findings. We sought a second opinion to verify the initial diagnosis and we wanted to enhance her chances of survival. Duke Medical Center's Bone Marrow Transplant Program (BMTP) for breast cancer patients was repeatedly and resoundingly ranked #1. They echoed the same diagnosis. Hence treatment began, immediately. Duke and the University of Iowa Hospitals and Clinics (UIHC) collaborated on her health care delivery.

Needless to say Kim was in shock, initially. She was searching for answers to: why me! Karetha, her sister, came to Iowa City from Chicago the same day that the diagnosis was received. She relocated within a week. She saw her task as provision of emotional support for both Kim and me. (Note: Their eldest brother, Victor Cortez Dodd died in a boating accident, August 2, 1981.) Theodore, my oldest living son flew to Durham and to Iowa City regularly from his home in Memphis, TN to lend assistance. Their father, Victor was stunned and overwhelmed; he had difficulty comprehending the significance/gravity of the situation at hand. He too journeyed to Durham and made numerous trips to Iowa City. And then there was me. I monitored her physical and psychological reactions and interactions with the most nurturing, caring and supportive teams of medical personnel, I've ever encountered. Her oncologist in Iowa City phoned us at home frequently; he anticipated problems, initiated consultations seeking alternative treatment strategies and provided ongoing feedback, returned my phone calls and even made home visits. The nursing staff was responsive, ever vigilant and tolerant. One of

the clinic nurses made off-duty home visits.

Pri^r to the beginning of chemotherapy, Kimberly cut all of her hair off rather than see it fall out; she was anticipating one of the side effects of chemotherapy. She loved her long "stresses" as she referred to them. Her reaction to each of the four (4) successive chemo treatments was progressively poor i.e. repeated hospitalizations for extensive periods of time, numerous blood transfusions and a medicine cabinet brimming over with drugs to counteract reactions to other prescribed medications. She underwent drug-induced menopause. She experienced mood swings. She prayed, talked and cried - but not one of her physicians prescribed mental health intervention or referral to a therapist for counseling. I attended to that need early on unbeknownst to them. I am a social worker as well as a parent. I heard what the surgeon said, that her emotional stability was paramount. She resisted initially for numerous reasons.

She quickly became very sophisticated in her capacity to relate physiological responses to need for meds and/or transfusions. She was extremely knowledgeable about the dosage and interaction effects of medications to her body. She was a stickler for precision and accuracy of care to her Hickman Catheter and portable medication pump. She initially dreaded learning to give herself injections of a growth factor. Later she injected all of her own meds when intravenous administration was the methodology of choice. This behavior was carried out both within and outside of medical facilities.

We all were in agony. Outside forces had joined to convince Karetha, her sister, to be begin law school. She tried to concentrate on her studies and I tried to work. I often wondered how long I would able to keep my job. You see Kim was seldom alone while hospitalized. For friends and family she put on a "happy face". She sent cards and letters, telephoning on special occasions and visiting between hospitalizations. All the while she was slowly deteriorating. She had no appetite, overall general weakness, unstable gait - often requiring a wheel chair for mobility. From September, 1992 to March, 1993 if she was not hospitalized, she generally spent most of the day in an out-patient clinic.

This whole process was completely overwhelming. Kimberly's pathology reports indicated that after her radical mastectomy (8/5/92), she was not an immediate candidate for a bone marrow transplant due to insufficient lymph node involvement for Duke's prescribed protocol. Because she was a randomly chosen subject in a clinical trial, we went to Duke in late August, 1992 (our third and final trip). While there (early September) preparing for the BMT, Kimberly found nodes which previously were not present. We remained in Durham for approximately six (6) weeks for the procedure. We then returned to Iowa City for the immediate initiation of a six (6) week course of radiation treatment. The time frame was controversial but fear of disease

progression required aggressive measures. Within weeks of beginning radiotherapy she was hospitalized - fever of unknown etiology and respiratory problems which mimicked pneumonia. The night prior to that admission she related her feelings of depression and frustration with her debilitating health status. She was admitted to intensive care and placed on a ventilator. Within two (2) days she was transferred back to the oncology unit. Her physicians consulted regionally and nationally. They attempted a number of treatment protocols but to no avail. Her red blood cell count was very low, her white blood cells were compromised, her heart was enlarged (reaction to earlier chemotherapy) and no one knew what was happening. Additionally, she was undergoing a personality change. Meanwhile she began to complain of pain in the right rib area. Yet, her left breast was the presumed primary site of cancer.

A change in medication restored her personality and she was discharged 12/21/93 with daily clinical assessment (that schedule included Christmas and New Years day). Late January, 1993, there was more evidence of physical deterioration. She could no longer be left at home alone. She could not ambulate without assistance. She had virtually no appetite. Her faith in God and hope for a miracle escalated. Karetha and I synchronized our schedules. Kim attempted to venture out to movies, shopping etc. but she tired easily.

She reported unbearable pain in her back along with ongoing discomfort in the right rib area and the appearance of two (2) nodules on the left upper arm (the area that was radiated). Her nights were sleepless. Repeatedly the doctors said that MRI and CAT-scan test results did not support metastasis. She was readmitted for further diagnostic workup i.e. biopsy. An orthopedic surgeon extracted tissue from her bone marrow (spinal area). It was a difficult and painful procedure. On 2/5/93 we were given the results - the disease had metastasized to her bone marrow, right rib involvement was confirmed and the two (2) nodes on the left upper arm were malignant. They estimated that she would live another four (4) months.

We had not been permitted to travel outside of Iowa City since returning from Duke - mid-October - due to fear of a medical emergency. In light of her situation I was allowed to transport her to Chicago to see friends and family over a long weekend. Her medical records were forwarded and she was equipped with a portable pump that injected pain meds 24 hours a day. She did not want pity. She dressed and applied makeup. She ambulated without assistance for as long as she could over the course of the weekend. No one could discern from her physical appearance that she was gravely ill. She just appeared thin which is not unusual for a twenty-four year old female. I had made it a point to insure that her clothing was appropriate/comfortable given her weight loss. She would not allow anyone to see that she was in pain. She required extensive rest periods and needed to recline when not ambulating.

She was readmitted to the hospital almost immediately upon our return. Her meds were increased, she barely ate, mobility was by wheelchair only, and her face was swollen the result of steroids. She befriended a young lady who was 18 years of age with cancer and who was a candidate for BMT. She had the chaplain pray for her, anticipated behaviors which might cause her discomfort based on her own experiences and modified her needs and that of her visitors to accommodate her. She even had me purchase a get-well card for this particular roommate. She began talking to her therapist, regularly. The chaplain approached her regarding hospice care. We wondered how much she really was consciously processing. The nutritionist could not get her to eat enough though she could order anything she wanted. We brought her meals into the hospital from home.

Kimberly point blank confronted medical personnel (residents) about her prognosis. They told her and attempted to estimate how long she would live. She requested a consult with her attending physician. She initially masked her emotional state, she was very good at that. But upon their departure she became hysterical. It was one of the few times she was alone without any of us (family) present. She called me at home; I was awaiting the delivery of medical equipment that she would need upon discharge. We spoke, I calmed her down as much as possible then telephoned the nurses' station to request meds and immediate support until I or Karetha could arrive. Kim was heavily sedated, Karetha sat with her. Her attending physician visited as well as the nurses from the clinic and the floor - to wish her well and to say goodbye. She was discharged from the hospital for the last time that day (3/10/93).

Kimberly had made it known that if she was going to die, it should be at home. Her room had been decorated with new bed coverings, a recliner, bright colors and the smell of potpourri. Home health services were in place. Karetha and I were taught how to administer meds intravenously and to manage medical equipment.

Kimberly was vain, there is no question about it! Heretofore she would not appear in public without makeup, wig and in full dress. Now she was bedridden, she summoned friends and family to visit her, presenting her fragile person for all to see without decor. She was jovial and warm to all comers. The end of her life was near and she knew it. She had grown ten-fold, emotionally. She reached out and comforted others. She no longer needed to be the center of attention. The pain was intense and she was in agony, physically. She requested that no life support technology be engaged. She seemed to have attained psychological harmony with herself and her God. Kimberly was no longer in denial or angry. She only wanted everyone to know that she was brave. She attempted to care for us. She gave us very explicit directions regarding her funeral services. The dreaded disease had spread from her left breast to the right ribs, to the bone marrow in her spine and possibly to her ovaries. She died less than a year

(eleven (11) months and three weeks) after the initial diagnosis on March 28, 1993.

Young women who are given the diagnosis of breast cancer initially experience an identity crisis, struggle with intimacy issues, experience deterioration in their sense of self-worth due to altered body image and presumed loss of control. Furthermore their sense of autonomy, loss of independence, and fear of social isolation given their health status can impair cognitive and psychosocial functioning. Health care providers do not always communicate in clear, direct and simple language. They protect themselves, the patient and their significant others (they think) by utilizing vague medical jargon. We tend to "blame the victim" consciously or unconsciously but early detection is meaningless for women with no familial history, under the age of forty, and pre-menopausal etc. The patient is placed in a position were they must accept responsibility and therefore feel guilt. Too often their response is withdrawal and fear of rejection. Kimberly experienced all of this and more, even though she was loved and supported. She frequently complained of loneliness - feelings of self-doubt and insecurity. I often felt that neither she nor I were able to effectively communicate what we felt. There were periods when she could only express anger which was directed toward me - but I understood the true source of her pain. I don't know if she understood that my brave, stoic and assertive demeanor was all that stood between reality and insanity. I questioned too: "Why wasn't it me instead of her? I would have traded places. "God surely wouldn't take a second child; what had I done, who had I hurt, why was I being punished?

Needless to say Karetha <u>just</u> wanted Kimberly to go into remission, so that they could realize their dreams of the "good life". Kim said that she wanted to attend a graduate program and major in social work. Theodore, her brother, and Victor, her dad, had their own issues. We all needed help!

If I could be granted wishes, I would ask for the inclusion of psychosocial assessment and mental health services as treatment protocol for every woman at the time of diagnosis and thereafter as needed. I want funds allocated for research to develop medications with less toxicity. I would add to that list, research to determine if disease progression for young women of african descent is different from their euro-american counterparts. Begin an immediate public service campaign targeting young women and ensure that breast self examination education is part of every wellness visit to a health care facility. And finally, reject the proposed age increase for suggested baseline mammogram per the National Cancer Institute. This utilitarian approach is not an answer. The identification and ulitization of an innovative screening and diagnostic tool with greater sensitivity and specificity is urged.

Mr. TOWNS. Thank you very much. Let me thank all three of you for your testimony. I know that when it comes to matters of this nature, it's very personal, and for you to come and share, I think is very, very important in terms of us trying to get to the bottom of this problem, to be able to save lives. And what you're saying to us, I think, is very important in terms of information, to be able to help us to further understand.

How do you feel when you hear the National Cancer Institute tell you, that mammography has not been proven by randomized clinical trials to benefit women between the ages of 40 and 49? How do you react to that?

Ms. DODD. I think it's unconscionable. I mean, those who have contradicted the study know that they have not looked particularly at African American women or any other women of color. They haven't looked at women. How can they come to a conclusion without including all of us who represent the United States? I have the sense that they're just throwing women away.

My daughter obviously is an exception to the rule because she was in her twenties, but the idea that she was a bright, intelligent, energetic young woman and that someone could say that we can afford to lose these people, that it's not important to us, that's ridiculous.

I certainly support the movement to set the mammogram baseline at age 40. I would, in fact, prefer to see it reduced further. But I'm more interested in NCI investing money and interest and time in looking at a diagnostic tool that's far more sensitive in the detection of breast cancer and is more specific in diagnosing it, for all women.

Ms. PETERS. I'm just incensed. And I think about 3 months ago I went over to NCI to pick up some materials, and as I walked through the halls, I understood why the public information campaign did not include me or did not refer to me in its message. I understood why, when I was diagnosed in 1989 when I was 39, I could not find information within my community on breast cancer. I had to go outside of my community.

The reason is, because I did not see any African Americans in the public information section, a whole wing of a floor. I walked up and down and got information and talked to a few people. Did not see, not one African American on the floor.

So the sensitivity, the understanding, even to connect to my ethnicity is not a part of the thinking process there. And so it is difficult for them to be able to really relate to the fact that we are being diagnosed, even though we may have the numbers, but to really connect to the fact that African American women are being diagnosed at a much earlier age and with a much more aggressive disease is difficult because they have no relationship to the African American community.

And I'd also like to introduce two very courageous young women. Ursula Brown is just 2 months out of chemotherapy, and she's 35. Doing well and looking good. And then we have Kathy Whitehead who is 33. She was diagnosed and treated within the last 9 months. So the numbers are there, and it was not difficult for us to find one another. It was not difficult for us to find one another.

So the figures are there, but they do not relate to us. They cannot connect to us. And I'm just—I'm incensed. I'm angry.

Ms. DODD. As I was stating, there may be a very different disease progression for women of African American descent. If you don't look at ethnic differences, and that's not to say that we're inferior by any means, but it just may be a deviation of the disease that you're not assessing.

Ms. PETERS. And it may also relate to our total experiences here in America. They may relate, but we don't know. There's not any focus or any direction or any studies in that direction to try and determine why we're afflicted and affected at such a greater rate and why mortality is just so much greater with African American women than for any other ethnic group in America.

Mr. TOWNS. Ms. Davis.

Ms. BROWN-DAVIS. And why reoccurrence occurs at a much greater rate in African American women than in other women. These are all things that need to be studied.

I was quite surprised when I heard of NCI's guidelines. It didn't register. It didn't make sense. Why would the foremost scientific organization in the world, why would their guidelines be so different from the American Cancer Society's? It didn't compute.

And then, when I further learned—and of course, this is information that, quite frankly, the average American citizen doesn't get, for a number of reasons—when I further learned that the study that these guidelines had been based on did not include any people of color, I thought, "This is really strange."

And so that's where I've been during the entire process, just thinking that it was very strange.

Mr. TOWNS. I see my time has expired. Let me yield to Mr. Schiff.

Mr. SCHIFF. Thank you, Mr. Chairman. I just want to take a moment to echo the comments that really all of the panelists made. As the panelists observed, it's not a matter of superiority or inferiority to say that different groups have different biological hereditities.

I'm a member of a group that suffers disproportionately from a birth defect known as Tay-Sachs disease, and that's the way it is. And I don't think that means we're above or below anyone else. It just means that for reasons that I think aren't totally understood, that occurs.

And speaking in general about the diversity of the United States of America and the people who live here, and, in particular, in my own district, the first district of New Mexico, almost 50 percent of my constituents are members of minority groups. I must say that the largest minority constituent group is Hispanic-American in my group.

But the point is the same. The point is, it's of great concern to me—and one that I hope will be explained by the representative from the National Cancer Institute—that I'm hearing over and over and over again that the guidelines that were adopted, or I should say maybe even eradicated, were based upon studies that not only are questioned just scientifically—I've heard that enough—but may not have included a sample population representative of the sample

population that lives in the United States of America, and that is served in particular by the National Cancer Institute.

Once again, as with the implication earlier of gender disparity in these guidelines, and the implication of financial pressures that are influencing medical judgment, I hope all of this is not the case, but I'm getting very afraid that it really is.

I yield back, Mr. Chairman.

Mr. TOWNS. Thank you very much. At this time I yield to Congressman Sanders.

Mr. SANDERS. Thank you very much, Mr. Chairman. I want to congratulate all three of you for your excellent testimony.

Mr. Chairman, this is a disturbing morning because the first panel told us what many of us knew to be true, that for a long period of time there was a great deal of sexism regarding government studies on health. And now what we're hearing is of equal concern because it may touch on racism.

Let me ask Ms. Peters, if I might, a question. You gave some statistics, and I didn't know those exactly, but, in general, I am aware that black women suffer from breast cancer at a greater rate than white women and die at a much greater rate, is that what you're saying.

Have there been good studies or are some being done to tell us what's going on? Might it have something to do with that the black community, in general, is poorer than the white community? Might it be environmental factors, work factors, whatever it is? Do we have some good studies behind us to begin to point out some reasoning for these very alarming statistics?

Ms. PETERS. Sir, if there are any studies, I'm not familiar with them, and I would say that none of us are—a very well maintained secret. I know of no studies that even begin to address the question as to why—particularly under 40, why the mortality—or the incidence is greater per capita and the mortality is just staggering comparatively speaking.

I have not seen any information coming out of the National Institutes of Health or the National Cancer Institute that would suggest they're beginning to proceed with such a study. I know their physicians are constantly seeing younger and younger women coming in and being scarred emotionally and physically for their life. Many are dying, leaving small children and young families behind. But they don't know of any studies.

Mr. SANDERS. Ms. Peters, am I correct that I'm also hearing you say that there is—or for any of you—that there is no public information campaign? What we're saying is, in general, what we want to do in terms of preventative health is target groups at risk, and what I'm hearing you saying is, African American women are at risk. That seems to be the evidence. One would assume, therefore, that there would be a campaign directed toward that population.

Am I hearing that there is not, Ms. Dodd?

Ms. DODD. There is one PSA on television that I've seen recently that has a black woman talking about the risk of breast cancer, but that was—the first time I saw it was about a month ago.

Prior to that, as I stated, and as Ms. Peters stated, breast cancer is perceived as a white women's disease, a middle class white women's disease. Poor black women don't develop breast cancer.

Mr. SANDERS. When, in fact, the contrary is the absolute truth.

Ms. DODD. The contrary is very true, and a great deal of energy has gone out in terms of public information and preventative health care to inform Caucasian women, Euro-American women.

Let me also state that—your previous question, when you were asking about studies, when my daughter developed breast cancer, we descended upon the health libraries at the University of Iowa looking for resources. There are very few studies available. The studies on autologous bone marrow transplant, the subjects were two people, OK? The numbers are so small in the studies it doesn't even matter. And the only sentences that we found that said anything about African American outcomes stated that they were fatal, they didn't survive.

Can you imagine what that's like? I don't have breast cancer. My daughter went to the library and read that on her own. Any other woman going to the library and seeing, "You've got breast cancer, you're dead."

We are not doing a good job at all in terms of educating women about the risk of breast cancer. Young women need to do every wellness exam, that they need to start or implement breast exams on themselves and with signs to look for. If you're not telling people about it, and particularly in that age group, young women, they don't look for it. They have no idea.

Mr. SANDERS. Let me just say this, Mr. Chairman. The conclusion is, I think you know that the primary reason has been a change in attitude toward women's diseases in general, and there has been in recent years. It did not come from the top. It came from hundreds of thousands of women like yourselves who are prepared to stand up and fight for it. It came from the grassroots.

So I congratulate you very much for your courage and urge you to continue the fight, because Congress responds and the bureaucracies respond to what takes place from down below. So congratulations, and thank you very much for coming.

Mr. TOWNS. Thank you very much, Congressman Sanders. At this time I yield to Congressman Mica.

Mr. MICA. Thank you all for your personal testimonies here today and relaying to the subcommittee your experiences. I guess cancer really doesn't know the difference between sexes or races, but sometimes our policies do discriminate, and we have instances of not addressing those problems, and part of our responsibility in Congress is to see that those policies are changed.

I'm afraid I have to get back, though. I mean, I've heard all of these instances, and I—you know, you hear like your daughter was in her twenties, and it sounds like every possible step was taken when she found it, and, Ms. Peters, when you found yours, Ms. Brown-Davis, and probably you all are the reason that we're examining this today, because there are probably a lot more people who are out there, women who are out there who, say, did not have the advantages you had or take the quick actions, and they end up——

Ms. BROWN-DAVIS. Dead.

Mr. MICA [continuing]. Not receiving the care and adding to the statistical base we've heard today.

Again, you heard my questioning of the previous panel, and again, we only have limited resources here, and that pool is shrink-

ing every day. So what do you think we should do as Members of the Congress with those limited resources?

When you see the lack of information—I mean, you went through this with your daughter, and you all personally went through it—that we don't have good information bases, and then we don't have research, and we also drag the bureaucracy or the agencies that deal with this in different directions and remain unfocused. Don't you think it would be better to try to get the basic information and do the basic research so that we can find cures across the board, or is that a wrong avenue?

Ms. BROWN-DAVIS. Well, of course, I mean, that's what any reasonable person would want done. The matter of where does that money come from, it's—I'm sure that the research possibilities are available. There are people trained to do the research. All they need is money and proper guidelines.

Mr. MICA. Well, in the area that you've discussed today here, as far as the higher incidence in minority populations, is there anything specifically we can do as far broadening the base of the studies, but anything else specifically that can be done?

Ms. PETERS. I think so. I think part of the problem is, there's a historical factor involved, and now we try and balance or equalize how we distribute the resources and how we apply them to various problems. But it's difficult when you've got a historical problem that has put one group at—if zero is the baseline, and one group is minus 150, and then you start—you know, you come today and you want to balance it out, and one group is at plus 10. Well, it's very difficult to start off on even ground with that.

So we are quite possibly reflecting some historical neglect, and so we've got to begin to address that in terms of trying to deal with the younger incidence within the African American community. We've got to be serious about having a public information and educational campaign that is targeted with—and not necessarily at—the African American community, because frequently when it's targeted at us, it misses us, because the people directing the target don't really understand who we are, what we are, and some of the uniquenesses about us. That needs to be addressed, and you cannot address it without including us in the process. That's a very, very, very important factor.

Mr. MICA. Ms. Dodd, did you have anything?

Ms. DODD. I stated my position that my interest was in PSAs, visual as well as written materials being distributed to women under the age of 50 who are of African American descent to make them aware of the incidence of breast cancer and their risk.

Also, I would like to see wellness programs target young women when they come in for their physical exams to educate them, again, around the issue of breast cancer. I have another bias, and it's separate from this, but it's that we don't address what's happening to a person psychologically when you're dealing with breast cancer. I'm sure that both these ladies and everyone else who's undergone a diagnosis of breast cancer has suffered psychologically and their families have been touched as well. You can't treat the body without treating the mind. It's a holistic approach once the diagnosis is given, and even prior to that in terms of education.

Mr. MICA. Thank you. You're all very brave and courageous individuals, and I know the subcommittee appreciates your testimony. Thank you.

Mr. TOWNS. Thank you very much. Let me thank all of you for your testimony. And, again, I thank you for coming and sharing with us your personal experiences. I think the information that you've given us will be extremely helpful. Thank you very much.

Now I would like to call Dr. Broder, Director of the National Cancer Institute. Since this is an investigatory hearing, I'm going to ask you to swear or affirm an oath. Will he be offering testimony as well?

Dr. BRODER. He very likely will. This is Dr. Sondik, my deputy.

Mr. TOWNS. Well, I'd like to swear him in, too.

Please identify yourself.

Dr. SONDIK. Edward Sondik.

Dr. BRODER. I'm Dr. Sam Broder.

Mr. TOWNS. And you're both with NCI?

Dr. BRODER. I'm the Director of the National Cancer Institute. Dr. Sondik is the Acting Assistant—or the Acting Deputy Director of the Cancer Institute.

Mr. TOWNS. Would you please raise your right hand?

[Witnesses sworn.]

Mr. TOWNS. Let the record reflect that the witnesses have answered in the affirmative. You may be seated.

Before we get to the questions, I would like to get some preliminary issues out of the way. Dr. Broder, I have two letters from the subcommittee addressed to you requesting documents relating to the subcommittee's investigation. One is dated January 13, 1994, and the other one is dated February 4, 1994. Did you receive them?

Dr. BRODER. Yes, I did.

Mr. TOWNS. And did the subcommittee receive all the information it requested?

Dr. BRODER. I believe it did.

Mr. TOWNS. On the contrary, the staff of my subcommittee has informed me that key documents were withheld from this subcommittee, which has delayed the investigation. In the interests of time, I will point only to two instances.

In the letter dated January 13 the subcommittee asked for all documents, including meeting minutes or any other documents relating to NCI's revision of its mammography screening guidelines. The subcommittee requested that these documents be delivered to the subcommittee by January 24, 1994.

Dr. Broder, can you tell me why the minutes or talking points from the executive meeting discussing mammography screening guidelines were delivered to the subcommittee only yesterday, March 7, almost 2 months later? Why did it take so long?

Dr. BRODER. I'll certainly discuss it with our Office of Legislation. My understanding is that approximately 500 documents were provided. And we'll certainly be happy to discuss with the subcommittee and provide any additional information, and I would be happy to specifically address any documents that you have or any issues that require clarification.

Much of the process that has been undertaken here is based on publicly available information, and I'm very sorry and apologize to

the Chair if there's any inconvenience on this point, but I believe that staff at the NCI have been trying to do the very best they can with the limited resources they have at their disposal.

Mr. TOWNS. Dr. Broder, I point to another key document that was withheld from us. In the February 4 letter the subcommittee requests all internal memorandums evidencing opposition within NCI to NCI's scientific analysis of mammography screening. The subcommittee requested these documents no later than February 14, 1994.

Dr. Broder, can you tell me why this memo that I hold from a researcher in the Early Detection Branch at NCI, that stated that the science shows a significant benefit from mammography screening, was not sent to the subcommittee by the deadline set in the January 13 and February 4 letters, and why did the subcommittee have to point blank ask one of your employees, Dr. Greenwald, who had supposedly sent us his entire file, for the memo?

Dr. BRODER. No, I cannot. And if the facts are as you state them, I will certainly remonstrate with the staff. There is no intent to withhold information.

All of the facts that I'm aware of that went into forming the decisions that the NCI has made are in publicly published materials. There are no secret meetings; there is no secret information that has been withheld from either the subcommittee or the public. All of the facts that went into this decision, painful and, in fact, difficult as it is, awesome as it is, were based on information which is in the public record. There is no confidential information, there are no discrete documents that are being withheld.

So I apologize for any inconvenience to the Chair, and I'm very sorry if that has caused any inconvenience, but I believe that, with my testimony today and with your ability to ask questions and, hopefully, for me to provide answers, you will be satisfied that a process has gone on and that it is public. Even if men and women of good will may disagree with the specific outcomes, the process has been quite public and open, including the publications of criticisms of what we've done in the same issues of journals in which we publish workshop reports and so on.

So I apologize to the Chair, but there is no—certainly not on my behalf, there is no attempt to withhold information, and we will certainly try to do what we can within the resources that we have.

Mr. TOWNS. Well, let me just say that, you know, when agencies do not cooperate, one begins to become a little paranoid about these things, because information is being requested, and we're not getting it. And, of course, your being the Director of the Institute we have to turn to you, and we expect you to encourage the others to cooperate.

Dr. BRODER. You are quite right to remonstrate with me if NCI staff have not fulfilled their obligations. I will take your concerns seriously. But I want to assure you personally here, under oath, that everything that we have done is done with open and candid disclosures, and where there is disagreement or opposition, we do not attempt to suppress that. In fact, we highlight opposition.

I believe there are members in the audience here who have been given the opportunity to publish their very learned and scholarly rebuttals or objections to the things that we've done. And so I be-

lieve that the basis for what we're doing is perfectly open, and I apologize if there are clerical or other misunderstandings. We have tried to respond as best we can.

Mr. TOWNS. Well, let me just say this, you know, Dr. Broder, just so we understand each other. I don't plan to go away. In my last election I got about 88 percent of the vote. So even if I drop down 10 percent, I still have 78 percent of the votes in my district. So I plan to be around.

Dr. BRODER. Sir, I hope you're around for a very long time.

Mr. TOWNS. I want you to know that so, let's see if we can establish the kind of tone and communication to be able to deal with some of these important problems.

I'm also troubled by NCI's sole reliance on randomized clinical—and we might as well put everything on the table—trials to the point of excluding other scientific medical and clinical data. Your testimony states that the science——

Dr. BRODER. Sir, will I be allowed to read an opening statement?

Mr. TOWNS. Yes, you will, yes—that the science doesn't show a benefit to women. What troubles me, is your total deference to the "science." I quote from a letter written by you to Dr. Russ Harris, one of the authors of the Fletcher report regarding the change in guidelines. In the letter you define your role at the National Cancer Institute in the following way, "Our job is to generate knowledge. We must stick to the science of what we do, whether we are dealing with a laboratory problem or a clinical trial. With your help we will not lose sight of our mission."

I ask unanimous consent that the full text of this letter and the letter written by Dr. Harris to Dr. Broder be inserted in the record.

[The information follows:]

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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December 17, 1993

Russ Harris, M.D., MPH
The Cancer Prevention Program
Lineberger Comprehensive Cancer Center
Trailer L, Mason Farm Road CB# 7300
The University of North Carolina at Chapel Hill
Chapel Hill, North Carolina 27599-7300

Dear Russ:

Thank you very much for your very kind letter dated December 7. This has been a very difficult but interesting period for the National Cancer Institute. We would not have been able to accomplish so much without your wonderful and generous support.

Scientists, such as yourself, are the National Cancer Institute. Our job is to generate knowledge. We must stick to the science of what we do whether we are dealing with a laboratory problem or a clinical trial. With your help, we will not lose sight of our mission.

With all my best for a Merry Christmas and a Happy New Year.

Sincerely yours,

Samuel Broder, M.D.
Director
National Cancer Institute

312-0125

North Carolina Prescribe for Health Project

The Cancer Prevention Program
Lineberger Comprehensive Cancer Center

Trailer L, Mason Farm Road CB# 7300
The University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-7300
(919) 966-4065 Fax (919) 962-2621

December 7, 1993

Samuel Broder, MD
Director National Cancer Institute
9000 Rockville Pike
Building 31, Room 11A48
Bethesda, MD 20852

Dear Dr. Broder:

I want to congratulate you and your fellow scientists at the National Cancer Institute for your approach to the breast cancer screening guideline controversy.

Despite intense pressure, people such as Drs. Barnett Kramer, Ed Sondik, Peter Greenwald Philip Prorok, John Gohagan and Larry Kessler were able to keep their perspective, and remain firm that NCI would make a clear statement, based on the evidence.

What you have done is courageous and extremely important. Your statement will have a strong and, I believe, positive impact in the community. But the implications go far beyond breast cancer screening. Many of us in the academic community now feel much more part of a larger effort, with you, to control the problem of cancer. We will all move forward together, basing our work on the scientific evidence.

Thank you.

Sincerely,

Russ Harris

Russ Harris, MD, MPH

cc: Barnett Kramer, MD, MPH
Edward Sondik, PhD
Peter Greenwald, MD,
Phillip Prorok, PhD
John Gohagan, PhD
Larry Kessler, PhD

Mr. TOWNS. As chairman of this subcommittee that oversees your institute, let me tell you today that I do not believe that science alone, to the exclusion of all other evidence on cancer detection, is the mission of NCI. If it were, I do not understand why Congress needs to allocate $2.1 billion—that's "b" as in "boy"—to NCI to conduct pure science. Your mission is to prevent, detect, and cure cancer, using all available evidence.

Your scientific subjects are not laboratory rats, but thousands of American women. NCI does not exist in a vacuum. Your actions affect people, many people. We're talking about human beings. You've heard today from the witnesses sitting at that table, their personal stories, stories of family members and friends. Your revised guidelines are not an experiment in any isolated lab out in Bethesda. This is the real world. We're talking about life and we're talking about death, Dr. Broder. So it's important that we share with each other to be able to deal with the problem that many people have been confronted with and others will continue to be confronted with if we don't openly begin to work together to deal with the problem.

Now, Dr. Broder, I would like to stop at this point and allow you to make your opening statement.

Dr. BRODER. May I please, with the Chair's permission, respond before my opening statement to what you've just said?

Mr. TOWNS. I'd be delighted.

Dr. BRODER. I hear what you say. I want you to know that the face of that young beautiful woman is in my mind and is one of the reasons why I'm doing my job. As an oncologist who's served with the U.S. Government for 22 years, I know that people die. My specialty is cancer and AIDS. So I want to assure you that whatever actions that we take, they are in recognition of the awesome—and I use that term in the full sense of what it means—the awesome responsibility that we have.

And if I could very briefly begin my opening statement.

Mr. TOWNS. Thank you.

STATEMENT OF SAMUEL BRODER, DIRECTOR, NATIONAL CANCER INSTITUTE, ACCOMPANIED BY EDWARD SONDIK, ACTING DEPUTY DIRECTOR

Dr. BRODER. Mr. Chairman and members of the subcommittee I'm Dr. Sam Broder, Director of the National Cancer Institute. Thank you for the privilege of appearing before you today. I'd like to thank the magnificent women who have testified today. Mr. Chairman, I'd like to submit my entire written statement for the record and take this opportunity to focus very briefly on certain points——

Mr. TOWNS. Without objection, your entire statement will be included in the record.

Dr. BRODER [continuing]. And some of these points are responsive to the legitimate concerns which you have raised.

It should be noted that mammography is an important and proven tool in women over 50, but it is not a perfect tool. A woman could have a tumor, even a palpable tumor, and a mammogram can, under some circumstances, fail to show it. Moreover, even when the intent is to screen women with no symptoms, it is my be-

lief that it is important for the doctor to talk to the patient and to know the patient. Sometimes patients who have concerns about their health, but are reluctant to voice them, ask for what they call a screening mammogram. For a variety of reasons the doctor should know, or try to know, when this is happening. Essentially, a mammogram is a tool for the practice of medicine, not a replacement for the practice of medicine. I know the difference between diagnostic and screening mammography.

There are important areas of consensus in the scientific community, and sometimes we lose sight of where we have a consensus and where we are in total agreement. We are in agreement that mammography has been proven, absolutely, in my opinion, proven, to be a valuable tool in reducing deaths for women over age 50, and, moreover, there is a clear and unmistakable consensus on this point.

Roughly 80 percent of breast cancers occur in women over age 50. For women under age 50 we do not have randomized clinical trial data to make such a statement, and we do not have a consensus among the scientific community. We need one or the other, but we can't lack both.

There is also a consensus that state-of-the-art treatment following a diagnosis of breast cancer is surpassingly important, and this fact is sometimes not highlighted in the discussions about mammography. It matters what you do. Mammography is just a preliminary to the process. It matters what happens to the woman after she receives a mammogram, but particularly if there's an abnormality.

This lack of agreement on the value of mammography, including its potential risks and benefits, for younger women stretches across the entire fabric of the National Cancer Program. It stretches between advisory groups, between scientists inside and outside the government, between doctors, and even between some groups of women's health consumers and other comparable consumer groups.

The key question, and one that should unite us, is how to go about reducing the devastating toll of breast cancer and other causes related to this problem.

When we have neither data from randomized clinical trials nor a scientific consensus to guide us, as a scientific organization, we have only one choice. I use the term "science" not in the term of laboratories and laboratory animals. I use "science" in the full and best use of that term applying knowledge, orderly rational knowledge to benefit and alleviate suffering.

We have only one choice: To stick to the facts as best as we can, and avoid attempting to make a pronouncement of policy where those conditions are lacking. Indeed, this philosophy is in alignment with a motion passed at the most recent meeting of the National Cancer Advisory Board, advising the National Cancer Institute to avoid independently attempting to set health care policy without cooperation and interaction of other relevant government agencies.

The deliberations of the Special Commission on Breast Cancer in microcosm illustrate the complexity of this issue we face. This body was established as a subcommittee of the President's Cancer Panel at the request of the vice president at that time in 1992. The report

was presented to First Lady Hillary Rodham Clinton in October 1993.

The President's Cancer Panel was then, and is now, chaired by Dr. Harold Freeman, a distinguished, brilliant scientist and director of surgery at Harlem Hospital. The Special Commission on Breast Cancer was chaired by Nancy Brinker, a breast cancer advocate and the founder of the Komen Foundation, a foundation that is devoted to making mammography accessible to women.

Nineteen distinguished scientists and breast cancer advocates conducted hearings and reviewed research. Two of the scientists, Dr. Dorit Adler, a radiologist specializing in mammographic breast imaging, and Dr. Gerald Dodd, a past president of the American Cancer Society and chairman of the Committee on Screening Mammography of the American College of Radiology, were members of the commission. The selection of these two radiologists was made with the specific consultation and approval of Dr. Louis Sullivan, then Secretary of Health and Human Services.

This diverse group examined many issues related to breast cancer, and they spent part of their time reviewing the evidence and addressing the issue of screening. They clearly noted the value of mammography in conjunction with physical exam, a point sometimes lost. Of the many facts that we have is that you should use mammography in conjunction with clinical breast exam. And this applies for women age 50 to 69. But they found the data regarding the benefit from mammography screening in women ages 40 to 49 inconclusive.

The background for the current NCI statement of fact has its roots in 1963 with the health insurance plan of greater New York. During the 1970's the breast cancer detection demonstration project was cosponsored by NCI and the American Cancer Society. In 1987 NCI developed working guidelines for the early detection of breast cancer. These guidelines provided the American public with a summary of the state of knowledge at that time. At that time evidence for screening was strongest in women age 50 to 69. This was based on the HIP study that included 60,000 women, 17 percent of whom were African American women.

The study included women ages 40 to 64, with all ages mixed together. The bottom line from the HIP study was that the best result that one could get seemed to be in women over 50. And even under 50 there seemed to be a considerable contribution of clinical breast exam.

Even at that time several nongovernmental and government sponsored groups, such as the American College of Physicians and the U.S. Preventive Service Task Force, an organization chartered to make such policy guidelines, did not go along with NCI's working guidelines recommending screening mammography in women under 50.

In view of the need for more definitive data, in view of the need for us not to appear to be focusing on laboratory issues versus the needs of human beings, NCI went ahead with the 1987 guidelines, but intended to revisit the guidelines should any new information become available.

As it turns out, for the population in whom the vast majority of breast cancer was found, roughly 80 percent of the breast cancer

occurs in women over age 50. The working guidelines that were undertaken in 1987 were, and are still, very relevant. I think that point is being lost. Eighty percent of what we did is still relevant.

In a sense, I believe the process for issuing the recent statement of fact began in 1991. In October of that year early unpublished results from the Canadian National Breast Cancer Screening Study were presented in closed session of the NCI Board of Scientific Counselors for the Division of Cancer Prevention and Control. Next, the Canadian National Breast Cancer Screening Study was published in November 1992 and did not show a mortality benefit for screening women in their forties after 7 years of followup. NCI began planning a major international workshop on breast cancer screening, and it was held in February 1993. Many of the scientists who performed the various key studies, as well as researchers in breast cancer screening, participated in this workshop. Results from all eight available randomized clinical trials of screening mammography were reviewed.

At the workshop a meta-analysis was presented by the researchers who used statistical techniques to combine the results of all the randomized clinical trials. This analysis raised questions and controversy about the value of screening between the ages of 40 and 49.

I would like to add a few thoughts on mammography as a technology. It was a bold advance when it was developed and various improvements have been made, both in film and machinery. But further investigation of conventional mammography, as the term is usually used, is unlikely to yield gigantic breakthroughs from additional refinement or studies of new applications. We do have hopes that some new technologies, such as digital mammography and magnetic resonance imaging and other new methods will improve imaging technologies——

Mr. TOWNS. Please summarize the rest of your testimony to allow the members an opportunity to raise questions.

Dr. BRODER. OK. In summary, we are seeking innovative ways of supplementing not only imaging, which addresses the issue of radiographically dense breast tissue of younger women, but also molecular and other screening technologies that might be of value in this approach and that will give us new knowledge.

We're in an era of very vast changes, a state of flux. We need to adhere to knowledge, we need to stick to the facts as best as we know them, and, particularly, we at NCI must use great caution when we oppose other government-sponsored groups that have standing to make comments unless we have facts. We need either a consensus or clinical trials, but where we lack both, we must stick to the facts.

Mr. Chairman, thank you very much for the opportunity of speaking to you.

Mr. TOWNS. Thank you very much, Dr. Broder.

[The prepared statement of Dr. Broder follows:]

To be released upon delivery

STATEMENT OF

Dr. Samuel Broder
Director
National Cancer Institute
National Institutes of Health
Department of Health and Human Services

on Mammography

before the
Subcommittee on Human Resources and Intergovernmental Relations
House Committee on Government and Operations

Representative Edolphus Towns, Chairman

Statement of Dr. Samuel Broder
National Cancer Institute

Mr. Chairman, and Members of the Subcommittee. I am Dr. Samuel Broder, Director of the National Cancer Institute (NCI). Thank you for the privilege of appearing before you today to discuss the NCI position on screening for breast cancer with mammography, the scientific basis for that position, and NCI's research on breast cancer.

The Impact of Breast Cancer

In 1994, about 250,000 women will die of all cancers combined, making cancer the second leading cause of death among women in the United States. About 46,000 women will die of breast cancer this year and it is the most common cause of death from any cause in women aged 40-44; however, over 80 percent of all breast cancer occurs in women over age 50.

Since 1987, breast cancer incidence, fortunately, has reached a plateau and appears to have decreased slightly. However, from 1973 until 1987, the incidence of breast cancer showed a steady increase. Although there appear to be slight decreases, the situation is still dire and indeed, breast cancer causes suffering beyond metaphor. Some of the increase in incidence during the 1980s has been attributed to increased detection due to mammography while the longer term increase is less well understood. We do not believe that the increase in breast cancer incidence can be fully understood without more basic research. We set our research priorities by recognizing areas of greatest need as well as by assessing those scientific opportunities that are nearest to clinical application.

NCI research has shown that the impact of cancer in general on minority and medically underserved populations is disproportionately great. For example, African-American women have somewhat lower incidence rates for breast cancer but higher mortality rates. In fact, African-American women over age 50 are at 20 percent lower risk of developing the disease than white women, yet their chances of dying from breast cancer are roughly 25 percent greater.

While our topic today is breast cancer and mammography, it is also important to note that African American men and women have high incidence and mortality rates in other cancers as well. For instance, African-American men have the highest prostate cancer rates in the world, and understanding why this is so is a very high NCI research priority. It is also worth stressing that for some cancers, for instance, colorectal cancer, the death rate among whites is actually dropping while the rate among African-Americans is actually rising. In my opinion, this is a warning. As we develop new knowledge and new technology, we must ensure that there is an equitable distribution of such knowledge and technology, or we will widen the gap. We must make sure that health technologies for women are widely available and accessible. In this context, we must recall that mammography is not an end in itself, but the prelude to treatment if treatment is needed. If effective and efficient treatment services are not available to women in need, mammography is, in one sense, of only theoretical value.

We at NCI are very aware of the often tragic situation faced by minority cancer patients. We have intensified our programs to reach minority and medically underserved groups. We scrutinize our programs for equitable treatment, we survey our clinical trials to ensure proportional representation, and we have developed a number of special outreach programs. In fact, it may be worth noting that the landmark Health Insurance Plan (HIP) of Greater New York study, the clinical trial that formed the basis of our first mammography screening guidelines included 17 percent African-American women.

Screening and access to screening procedures are only a few aspects of this very complex situation, one that tangles economic issues, educational issues, access to state-of-the-art treatment and follow-up care with many other variables including molecular and environmental ones. Many of the challenges we face as a society are outside the mission of a research institute.

The Role of Mammography

Mammography, in the era prior to health care reform, seemed to be a successful way to introduce some underserved women into the medical system. Mammography lent itself to community outreach. A van could go into the community, and a woman who had never seen a doctor could have a mammogram. If she had suspicious signs, she could be ushered into the medical system. Indeed, screening mammography sometimes provided an entree for many different facets of women's health, including information and education ranging from nutrition to high blood pressure control. Indeed, many private and public organizations, including NCI, worked to make this a successful outreach effort, and as a society we need to make sure that whatever is done in health care reform fills this void. Mammography in some settings became a symbol for concern about breast cancer, even a way a woman could express her self-determination to protect her health. But mammography should have never been expected to do all that--it is a medical tool, nothing more and nothing less.

Mammography was designed primarily to be used to screen for breast cancer or for diagnosis and where it is effective and where there are other benefits, that is all to the good. Thus, for women over 50, mammography is an established but certainly not a perfect, screening tool. But there is extreme disagreement in the scientific community concerning women under age 50, and there is no consensus that mammography will reduce mortality in this age group. Regarding mammography, we must state what we know and what we do not know. One thing we do know: any woman who finds a lump or something else wrong with her breasts should seek a consultation with her physician, even if her mammogram has been read as normal. And, as I will discuss later in more detail, the doctor should listen to the patient and should know the patient.

The issue of mammography is an area of intense polarization between various groups at this time. The polarization has occurred not because of fundamental differences--we all share the concern that women are dying of breast cancer--but because we have different perspectives on this problem. We have a lack of agreement on the value of mammography (including its

risks and benefits) particularly for younger women. This lack of agreement is between scientists (inside and outside the government), between doctors, and even between some groups of women's health consumer advocates and other comparable consumer groups. Sometimes the debate has been scholarly and productive. Other times, it has produced more heat than light. The key question and the one that should unite us is how to go about reducing the devastating toll of breast cancer and other cancers using the best facts available.

The suggestion has been made that NCI should begin a new mammography clinical trial to find a solution to the problem of screening in young women. This issue is open to discussion, but we need a careful review of all of the issues, including how to adapt emerging technology and an assessment of how to efficiently utilize clinical trials that are already underway. As with any area in which human subjects are involved, it is important to operate at the highest ethical and scientific level using contemporary standards.

Mammography was a bold advance when it was developed a number of decades ago. Various improvements have been in made in both films and machinery. But, further investigation of conventional mammography, as we now know it, is unlikely to yield truly dramatic breakthroughs from additional refinements or studies of new applications. Even though we believe we are already fully exploiting the strengths of mammography, we do believe that some new technologies such as digital mammography and magnetic resonance imaging and other new methods which will improve imaging capabilities.

Indeed, this is an very unusual time of flux in the science of breast imaging. We are continuing to stimulate the development of innovative methods of imaging the radiographically denser breast tissue of younger women--tissue that can be exceedingly difficult to image with conventional mammography. And we continue to work toward simple screening tests, possibly blood tests, that would pick up molecular evidence of breast cancer or breast cancer susceptibility, and at the same time, might be the basis for new and effective therapies.

Moreover, we must realize that screening mammography is not true prevention, and we are pursuing a vigorous multi-faceted cancer prevention research agenda.

Clinical trials are a proven way to move a new experimental technology from the laboratory to the clinical care of patients. This process has taken place with mammography. In the United States today, it would be no easy undertaking to randomize a woman to a control group with no intervention or to an intervention not selected by the woman. We are exploring other types of research methodologies, such as the case-control study design planned for use in the Long Island Breast Cancer Study Project, to serve as possible alternatives to randomized clinical trials in assessing environmental risk factors.

Randomized clinical trials are developed out of a simple concept of comparing one approach to another. But putting them into operation is often very complex. In general, randomized clinical trials involve a fair, dispassionate (i.e. computerized) assignment of individuals to one group receiving an experimental intervention or to another group receiving no experimental

intervention. It should be emphasized that in our society it is usually no simple task to implement such trials either from a scientific or ethical point of view. Indeed, sometimes the ethical imperatives of conducting large-scale, long term randomized clinical trials are awesome.

If there is a body of evidence and even a tentative conviction on the part of clinicians that some interventions work, it becomes difficult to randomize people to a placebo or to a no-intervention control group. To randomize some women in a breast screening trial would mean, in effect, that a computer would tell some of the volunteers not to have mammography. People who volunteer to participate in clinical trials must give an informed consent and be aware of all the potential risks and benefits, and they must have the right to drop out at any time. There is often nothing to prevent them in effect, from crossing over to the other arm of the study.

The more strongly held views there are about a technology at the outset, the harder it becomes to randomize a person to a no-intervention group. We never want to harm women or reduce their chances at diagnosis or cure simply to conduct research, nor would we conduct a clinical trial on a vulnerable underserved target population when we would not be likely to conduct such a trial for the population at large.

We are currently exploring other clinical research methodologies (such as the case-control study design) that could, in some settings, provide an alternative to controlled, randomized trials. But many alternative methodologies such as case-control, case-fatality, and other research approaches are subject to selection bias and other hidden errors that vitiate the results. In addition, the scientific community can very seldom reach a consensus on the basis of a single paper or single analysis. It is also important for us to forthrightly face up to results that don't necessarily come out the way we might want, or else we may find out that our analysis simply confirms what we thought we knew at the beginning.

Thus, randomized clinical trials represent the gold standard for clinical research, and at this time, many of our best experts will accept no results other than those produced by such trials. When a tentative conclusion is reached through a case-fatality or other research analyses. but contradicts the bulk of the data from randomized trials, these scientists will opt for the randomized trial result. Randomized trials take years to complete, first to design the research, then to enroll patients, and then to actually carry out the trial--often 10 to 15 years--and then, last but not least, to analyze the results.

These are not easy issues, and there is virtually always a dynamic tension between implementing what we know and conducting trials to nail down additional facts. Sometimes we have to act on the basis of interim results and, at the same time, continue the randomized clinical trial process. But where the results of randomized clinical trials do not support the results of other methodologies such as the case-control or case-fatality method, the results from randomized clinical trials must take precedence. There are no simple answers, no easy short-cuts, and it is a mistake to assume that any one simple formula will resolve the

enormous complexity we face. These types of statistical questions are among the most complicated in science today. These realities apply to cancer, but very similar complexities exist in AIDS and many other fields.

Chronology

A very brief historical perspective may be useful. The Health Insurance Plan of Greater New York was a landmark randomized clinical trial on mammography and clinical examination. In 1963, the HIP study began to enroll 60,000 women from the ages of 40 to 65 who had been HIP members for at least a year. About 30,000 were given screening and clinical examination while a comparable number of women were not offered screening and were asked to follow their usual medical practices, which, at the time, would not have included screening mammography as a general rule. The study took several years to accrue enough patients. Follow-up extended for about 18 years. The overall reduction in deaths due to screening in this study was largely due to the impact on women over 50 years of age. There was a contrast between the older and younger groups, with mammography appearing less useful in the younger women in the HIP study, but more information was needed. And there was a uniform hope that mammography would be found to work in all age groups.

In short, even this intensive and extensive trial needed subsequent studies to allow for more precision and accuracy in information about screening. Some researchers would have been willing to wait for more trials without acting. Yet many scientists, including those at NCI, believed that the HIP study provided enough information to initiate screening practices while at the same time conducting research to seek more information.

We believe this was the right course of action. We did our homework. We did confirmatory analysis (such as applying the case-fatality methodology to the HIP study and analyzing various demonstration projects.), and we recommended mammography for a wide age group, including women over age 40. One of the most important programs of the 1970s was the Breast Cancer Detection Demonstration Project (BCDDP), co-sponsored by NCI and the American Cancer Society (ACS). To show how complex the history of this topic really is: in the spring of 1977 the project's directors and advisors recommended restricting the routine use of mammography in those women under age 50 with no family history, in part because of concerns in that era over radiation doses. Thus, for various reasons and at various times, the NCI has modified its recommendations for younger women.

For a period of time, there were rapid improvements in the quality of mammography and access to such screening, and hopes were high that all tumors could be found at an early stage and that finding such tumors would lead to more cures. During this time, a number of brave women who were in the public eye spoke candidly about their disease; as a result, breast cancer was more discussed and more understood and women and their doctors were seeking answers.

Certain clinical studies continued, including a major randomized trial in Canada, for which many physicians and patients alike had high expectations. And yet, there were concerns even then that, in some young women, certain tumors could be invisible on conventional mammography screening, sometimes even when the tumor was palpable on clinical examination. And as our knowledge of the biology of breast cancer grew, there were also concerns that some tumors may shed microscopic deposits of cancer cells into distant parts of the body even when the tumors are exceedingly tiny and undetectable with our present technology, and it is those cells that have spread, not the primary tumor, that ultimately kill women as a general rule. This fact that some tiny tumors can metastasize quickly confounds the prophecy that if a tumor can be detected very quickly, the patient can be cured. Early detection in many types of cancer certainly makes sense, and we should vigorously pursue early detection whenever the scientific facts support it. Yet, in some women, it is a tragic fact that the biology of their cancer determines their fate from the earliest moments. In such cases, survival may be determined by whether a woman receives state-of-the art therapy (including adjuvant chemotherapy) once a tumor is found.

The NCI Mission

The NCI is a science institution, a biomedical research institution committed to generating the knowledge needed to reduce the suffering and death from cancer. While at times there have been bursts of enthusiasm for research advances that promised to cure cancer, we all recognize that cancer has, in fact, not been cured. Today, there are exciting developments on many fronts, particularly in basic research, and as we discuss these successes, we must acknowledge that cancer poses an awesome research and therapeutic challenge. We must have no illusions on this point. We must be always be clear on what we know versus what we hope.

As a scientific organization, we know that individual opinions and practices may require adjustments or fundamental changes as we learn more facts about normal biology, as we learn more about the cancer cell, and we have more opportunity to assess diagnostic tools and treatments. At the same time, we have seen that yesterday's "incurable and fatal" disease can be tomorrow's medical triumph and that a disease that relentlessly terrorizes one generation can be only dimly remembered by the next one. Two principles must guide government agencies whenever possible: the consensus of scientific peer groups and/or clinical trials as the instrument for consensus wherever possible. Sometimes we have both a consensus of peer groups and randomized clinical trials, sometimes we have one, sometimes we have neither to guide us. Where we have neither we must be very cautious about pronouncements addressing wide spread use of technology implying known, proven efficacy.

Each of us has a role to play in this enormously important effort to save the lives of American women. I believe that NCI's role is the generation of knowledge, the sharing of that knowledge and translation of scientific knowledge into clinical reality at the community level. We might well implement a treatment on the basis of an interim analysis or evaluation, but we would certainly not continue to advocate that treatment if followup

randomized clinical trials showed that its benefits were initially overstated, that in truth, it brought no reduction in deaths in the real world. In the world of screening, the same holds true. Certain tests--such as screening chest x-rays for lung cancer--are no longer recognized as valuable for reducing lung cancer mortality, and here, as with mammography, we must tell the public the facts.

By the same rules, we must adhere to what we have learned about the value of mammography for women in various age groups. If we can achieve a consensus, fine. If not, we must permit the results of randomized clinical trials to serve as a check and balance on what we have done in the past. After a process of scientific evaluation, after extensive review of data from a number of randomized clinical trials (including the just completed study in Canada), after internal and external debates, and most important of all, after seeking the input and advice of our most respected non-governmental experts, we have an obligation to share the results of this process with the women of America.

We owe it to American women to provide the most accurate information available about screening and treatment of cancer at a point in time and when there is intense scientific controversy, we cannot insulate women from such facts. If a woman asked us "Why do you recommend mammography?" we have to answer her question.

We have to tell them our conclusions and the research base for our decision. We can safely say based on clinical trials and a wide-based consensus that, in the case of mammography, a routine program of screening will definitely save lives for women over 50 years of age. This technology has been proven in randomized clinical trials for women over age 50, and in addition, there is a clear and unmistakable consensus on this point. For women under 50, neither condition applies at this time, and whatever we tell women, they would need to be told this. We believe the woman and her doctor need to discuss the facts and then to take a course of action based on those facts.

Screening versus Diagnostic Mammography

One point must be emphasized: we are focusing on screening, a process done on large numbers of women who are free from signs or symptoms of disease. This discussion does not address diagnostic mammography, where a doctor and woman are joined in evaluating symptoms or other indications, such as a lump, pain, or swelling, of a possible malignancy. That is a different situation entirely, and in evaluating a woman with symptoms, mammography in conjunction with other diagnostic tools is considered as standard procedure at any age. I also want to stress that when a doctor's clinical judgment and knowledge of a particular patient coupled with an informed discussion of the patient's concerns, leads to a decision to undertake mammography (screening or diagnostic), we at NCI would gladly defer to the sanctity of the doctor-patient relationship.

We would want the patient to be made aware of the facts (including a discussion of the possible negative features, not just the positive features) as they are known about the

procedure or the treatment, but the patient-doctor relationship must be protected and respected. Moreover, we believe that a doctor should carefully listen and determine whether any individuals requesting screening have a suppressed fear or are subtly expressing a concern about their health, even if they cannot put it into words. All of us know it is sometimes difficult to raise such issues directly. A doctor should inquire and try to elicit if there is an unspoken factor in the equation. What is sometimes lost in our discussions is the point that mammography should be an adjunct to the practice of medicine, not a replacement. Even under the best circumstances, there are times when a breast cancer is first detected by clinical exam or self exam in spite of a regular program of screening mammography. All in all, the doctor must listen to the patient and must know the patient.

Doctors and patients rely on and make life and death decisions based upon many kinds of test results. As scientific knowledge matures, each of these tests is revisited, and sometimes their value is affirmed, sometimes questioned, and sometimes discarded. It is important to note that mammography is only one of several technologies being examined by NCI. For example, NCI's large randomized clinical trial, the Prostate, Lung, Colorectal, and Ovarian (PLCO) trial, has begun to evaluate screening tests in these cancers. This study will assess the predictive value of the widely used test for prostate specific antigen (PSA) and less used technologies such as ultrasound, CA 125 or flexible sigmoidoscopy. In women, for instance, the study is designed to determine whether screening with pelvic examination plus serum CA 125 and transvaginal ultrasound can reduce deaths from ovarian cancer. Thus, for such tests as PSA and CA 125, we are not recommending their adoption as routine screening tools until clinical trials, or at least a scientific consensus, permits us to do so. This is the same philosophy we are bringing to mammography.

NCI supports research aimed at locating important genes and genetic processes in breast cancer. Research is being carried out on specific inherited gene abnormalities and certain familial predispositions to breast cancer including benign proliferative breast disease: the Li-Fraumeni syndrome, in which family members inherit a mutation in the p53 tumor suppressor gene located on the short arm of chromosome 17, and early-onset familial breast cancer, linked to abnormalities also on chromosome 17, referred to as Breast Cancer-1 or BRCA-1, to name but two.

Collaborations with the National Center for Human Genome Research are designed to elucidate genetic information about breast cancer. On December 2, 1993, we were pleased to announce the finding of a gene for colon cancer that also appears to play a role in ovarian, uterine, and several other cancers. When genes are found, tests can be developed to show which women are at risk. Sometimes the genetic discovery will aid in developing vaccines or new prevention strategies.

At times, conditions not typically thought to fall within a definition of women's health are of surpassing importance. Thus, the gene for Ataxia-Telangiectasia, when carried by an otherwise normal woman, may predispose her to radiation damage and breast cancer. We are vigorously trying to identify the responsible gene to identify those women who should go out

of their way to minimize radiation (x-ray) exposure. As carcinogenesis studies progress, this information could theoretically be used to counsel women at high risk to avoid certain environmental exposures (including x-rays) and to undertake individualized programs of screening and prevention.

Genetic discoveries will yield new molecular tests that might have high specificity. But we are not waiting for these events to occur. We are working to refine our knowledge of the tools we have, including mammography. In September 1991, NCI held a workshop entitled "Breast Imaging: State-of-the-Art and Technologies of the Future" and plans another in the near future. Because of the promise of digital mammography, a working group was formed to focus on this technology. We are encouraging the development of new digital mammography techniques, which would also allow transmittal of images for consultation or diagnosis by specialists. New imaging techniques are being used to more accurately guide biopsies and surgery. Other methods are borrowing from technology developed in space or defense research. None of us is content. We know first-hand the suffering caused by this disease.

A word about the specific history of NCI recommendations is in order. In 1987, the NCI developed Working Guidelines for the early detection of breast cancers. These guidelines provided the American public with a summary of the state of knowledge at the time. They were made in order to crystalize the best thinking at the time, but with the understanding that if crucial new information became available, the guidelines would be modified. As it turns out, for the population in whom the vast majority of breast cancer (women over age 50) is found, the recommendation is still basically correct. Thus, to a large extent, these 1987 guidelines were the right thing to do in that 80 percent of breast cancer cases occur in women over age 50. The NCI did not make a mistake then, and we do not believe we are making a mistake now. [1]

At the time these guidelines were developed, evidence for screening was strongest in women ages 50-69, although the Health Insurance Plan of Greater New York clinical trial had shown a reduction in cancer deaths for all ages mixed together due to screening in this study of 60,000 women aged 40 to 64 at the inception of the study. In all fairness, even then, several

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[1] 1987 guidelines

--The screening process should begin by age forty and consist of annual clinical examination with screening mammography performed at one to two year intervals.

--Beginning at age fifty both clinical examination and mammography should be performed on an annual basis.

--Physicians should encourage women to perform monthly breast self-examinations.

non-governmental and governmental groups (such as the American College of Physicians and the U.S. Preventive Services Task Force) opted not to go along with these guidelines and did not recommend screening mammography in women under age 50. NCI considered the above guidelines to be working guidelines with the clear intent to revisit them should any new information become available. Many experts feel that the time for revisiting them has come.

Re-evaluating NCI's Position

Several events have led to an ongoing re-evaluation of the breast cancer screening guidelines.

- First, an NCI-supported meeting entitled "Forum on Breast Cancer Screening in Older Women" was convened in April 1992. Among the recommendations was the following: "There was enough direct evidence to support a recommendation for universal screening in women sixty-five to seventy-four years of age. Because of the lack of direct evidence regarding screening efficacy and because of increasing occurrence of multiple chronic diseases in women seventy-five years of age and older, the Forum concluded that clinical judgment was necessary to weigh the relative benefits of co-morbidity and screening effectiveness for the individual patient in this age group. Regarding the interval for mammography and clinical breast examination, the Forum concluded that there was no evidence to choose one interval over another, since apparently equally effective intervals have ranged from twelve to thirty-three months."

- Second, the Canadian National Breast Screening Study of screening women in their forties, published in November 1992, did not show a mortality benefit ascribed to mammography after seven years of follow-up. This was a randomized controlled study. Dr. Anthony Miller presented a preliminary analysis of this study in closed session to the Board of Scientific Counselors of the NCI's Division of Cancer Prevention and Control (DCPC) as far back as October 1991. To be candid, this was certainly not the answer we had hoped for. But we cannot allow hope to obscure facts.

- Third, an overview analysis (a meta-analysis) of five randomized screening trials conducted in Europe in the 1970's was reported early in 1993. The study found that the largest reduction of breast cancer mortality, roughly one-third, was observed among women aged 50-69 at randomization. Among women aged 40-49 at randomization, no statistically significant difference was observed.

I would like now to briefly discuss the process by which NCI came to the specific change under discussion today, but before doing so, I want to put to rest the concern that the NCI's position is influenced by political considerations or expediency.

This process of re-evaluation was initiated in 1991. It was obvious that there was a need to evaluate the new information in the context of the large body of evidence that had evolved since the landmark HIP study of thirty years ago. Until recently, the HIP study was the best body of evidence for the benefit of screening. There is still one conclusion from that study that is relevant today: mammography has similar benefits--or lack of benefits--for both African-Americans and whites. It is our best scientific thinking that in the prevention and treatment of cancer, techniques that work, work in both groups. Those that fail, fail in both groups. It is also worth noting that the benefit ascribed to mammography in the HIP study is, on balance, as good a result as any achieved in subsequent randomized trials.

The next phase occurred following a pre-publication, closed briefing in fall 1991 on the Canadian mammography study. NCI began planning a major international workshop of breast cancer screening that was held in February 1993. Many of the scientists who performed the studies, as well as researchers in breast cancer screening fields, participated in this workshop. Results from all eight published randomized clinical trials of screening mammography were reviewed. At that workshop, an overview analysis, called a meta-analysis, was presented by expert researchers who had examined all the randomized screening trials in the world. This analysis raised questions regarding the benefit of screening women between the ages of 40-49. This workshop was open to both the press and the public. At that time, NCI provided information and resources to the media; interested voluntary, advocacy, and health professional organizations and the public on the mammography screening studies that were being reviewed.

The final report of the workshop concluded the following:

- First, "The randomized trials of women ages 40-49 are consistent in showing no statistically significant benefit in mortality after 10-12 years of follow-up. For this age group, it is clear that in the first 5-7 years there is no reduction in mortality from breast cancer that can be attributed to screening. There is an uncertain and, if present, marginal reduction in mortality at about 10-12 years. Only one study provides information on long-term effects beyond 12 years, and more information is needed."

- Second, "For women ages 50-69, the evidence presented at the Workshop strengthens the scientific observation that screening leads to reduced breast cancer mortality. Every study presented found a protective effect for women in this age group. The Swedish studies suggest that a screening mammogram as infrequent as every 33 months reduces breast cancer mortality, at least in a population with a high compliance rate and in a setting with high-quality mammography. These data raise the possibility that a screening interval of every 12 months may not be necessary in this population."

- Third, "Women in their 70's are a high risk group for breast cancer. The currently available clinical trial data for these women are inadequate to judge

the effectiveness of screening because the numbers of women were small, the compliance was poor, and the screening episodes were too few."

The Workshop charge was to critically review and summarize the scientific evidence, not to develop guidelines. In response to this analysis, NCI staff began the process of reviewing our Working Guidelines in the context of the new information. NCI has a responsibility to provide accurate, clear information to the public based on scientific evidence. This information clearly held an important public health message for all women and health care professionals.

Subsequently, the following process has taken place:

♦ During the period from March through August 1993, the NCI PDQ Editorial Board, consisting of both government and non-government researchers, independently reviewed and endorsed Workshop results; the NCI PDQ Editorial Board developed draft guidelines-recommendations that were reviewed by the NCI Executive Committee to stimulate and focus the discussion. During the summer, a decision was made to limit the PDQ statement to a summary of the scientific evidence on cancer screening. Around that time, NCI staff also met with the American Cancer Society (ACS) to discuss principles underlying the NCI draft guidelines. Subsequently, by the end of August, NCI had developed a draft of guidelines for breast cancer screening for the purposes of focusing the discussion.

♦ In September 1993, the draft guidelines were reviewed and discussed by PHS agencies and selected participants from the February 1993 International Workshop on Breast Cancer Screening; NCI staff met with the ACS Breast Cancer Subcommittee, the National Cancer Advisory Board, and with individual members of the DCPC Board of Scientific Counselors to discuss proposed guidelines.

♦ During October 1993, NCI disseminated draft guidelines and other materials to agencies involved in earlier guidelines and voluntary advocacy groups, with a request for written comments and attendance at the upcoming October 21 meeting of the NCI DCPC Board of Scientific Counselors.

♦ On October 21, 1993, the guidelines were reviewed by the DCPC Board of Scientific Counselors, which passed a motion recommending that the existing recommendations for women 50 years and over be maintained and that for women under age 50, NCI provide a summary of existing evidence and data and suggest that these be discussed with each woman's physician or health care provider. In effect, the Board wanted to present the facts without the pronouncement of a guideline.

♦ Meeting on November 22-23, 1993, the National Cancer Advisory Board passed the following motion: "Recognizing that there is controversy on the effectiveness of

mammography for women under the age of 50 that calls for more research, the members of the National Cancer Advisory Board recommend that the National Cancer Institute defer action on recommending any changes in breast cancer screening guidelines at this time."

♦ On December 3, after careful consideration of the conflicting advice of scientific experts, NCI released the following statement summarizing our position on breast cancer screening:

> "There is a general consensus among experts that routine screening every 1 to 2 years with mammography and clinical breast examination can reduce breast cancer mortality by about one-third for women ages 50 and over.
>
> Experts do not agree on the role of routine screening mammography for women ages 40 to 49. To date, randomized clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50."

♦ Shortly after the NCAB meeting, in early December there were other important comments including a statement by Dr. Paul Calabresi, chairman of the NCAB saying as follows: "I am extremely pleased by the nature and substance of the NCI statement. I think the recommendations are both accurate and appropriate. NCI is a science-based organization and the statement represents an excellent summary of scientific fact." Dr. Howard Temin, a Nobel laureate who died in February, and a long-term member of the NCAB, wrote to Secretary Shalala on December 7, 1993. In his letter he supported the "NCI statement of fact about breast cancer screening that was released last week. I think that the recasting of the National Cancer Institute as a science institute is most appropriate. Health care is much too complicated for us to be involved in without much more study."

♦ On February 23, 1994, the NCAB unanimously passed a motion (with one abstention) as follows: Inasmuch as cancer research is the primary mission of the National Cancer Institute, the NCAB recommends that the NCI not involve itself independently in the setting of health care policy."

Therefore, NCI now is in substantial agreement with the spirit of the NCAB motion that the generation of knowledge and the dissemination of factual information, but not the formulation of guidelines, is the proper role of the NCI.

The change has been controversial, but the process has been open and candid. One of our chief concerns is to be sure we give women the unvarnished facts as best as we know them now. There are large areas of agreement. There does appear to be a consensus that the positive predictive value of mammography--that is, the ability to detect a tumor--in younger

women with no family history is significantly less than in women over age 50, whatever individual views are held about the larger issue of mammography in that age group. There is also a consensus that state-of-the-art treatment following a diagnosis of breast cancer is surpassingly important, and this fact is sometimes not highlighted in discussions about mammography. We have extended our outreach to many diverse groups, both scientists and consumer advocates. We have heard from women's advocates who strongly oppose the use of routine mammography in women under 50 and those who, with equal strength and eloquence, hold the opposite view. We know of nothing that will change this reality in the foreseeable future.

NCI has been intensively reviewing the state of the science regarding mammography screening efficacy for at least two years with a keen awareness of how important, indeed, how awesome, was our task. After the Workshop conclusions were clear, NCI conducted surveys and focus groups with women and health care professionals to anticipate issues that might help to prepare health professionals and the public for such changes.

Results from the surveys and focus groups indicated women clearly understand that scientific debate on health issues is sometimes unavoidable. They do not want to be artificially shielded from such debate. The actual decisions about mammography will need to be made by an individual woman in a dialogue with her health care provider after she weighs and consider the pros and cons. Our focus groups suggest that some younger women will continue to ask their doctors for mammograms. If facts inform the decision, we will have done our job.

The NCI maintains communication with many voluntary, advocacy, and health professional organizations in the areas of cancer prevention, early detection, and treatment. NCI has redoubled its efforts to stay in close communication with these organizations and to assist, when possible, in minimizing the confusion that often occurs when scientists revisit a situation. Yet, we sometimes must differ even while we may, at the same time, respect and admire those who disagree with us.

On December 3, 1993, NCI released the new mammography statement and simultaneously communicated with all its units--including the Cancer Information Service, which answers inquiries via the toll-free 1-800-4-Cancer telephone number, the National Black Leadership Initiative on Cancer, the National Hispanic Leadership Initiative on Cancer, the Appalachian Leadership Initiative on Cancer--and outside groups such as the Cancer Centers Public Affairs Network, and the Centers for Disease Control and Prevention to determine the strategies and tools needed to convey NCI's breast cancer screening messages in light of the latest scientific review. NCI immediately began updating its own publications and developing a consumer brochure that explains the new position on breast cancer screening for women 40 and over.

The NCI Division of Cancer Prevention and Control has met with organizations within the Public Health Service to determine how best to work together on this issue and to organize an

ad hoc committee of NCI staff as a first step to develop effective strategies to educate physicians and other health care providers on the new NCI mammography statement.

NCI staff will continue to meet with breast cancer advocacy groups and voluntary organizations, such as the American Cancer Society (ACS), to clarify issues, identify common ground--and there is common ground--foster cooperation, and explore joint communication efforts, when this is possible.

Perhaps most important, we will continue our research agenda. In the near future, we will be holding a workshop to summarize the state of science for breast cancer screening. We will continue to review what technologies hold the greatest promise for progress and what additional studies need to be done. We will strive for consensus.

Mr. Chairman, I welcome your interest and the interest of this Committee and the Congress in this issue. You represent a strong advocate for American women. Please allow me to say once again: Each of us has a role to play in this enormously important effort to save the lives of American women. NCI's recommendations must be based on scientific evidence to the greatest extent possible, and they must change as new information becomes available. Please note that answers to the questions raised by the Subcommittee are answered in an addendum. Thank you, Mr. Chairman, for this opportunity to testify. I would be pleased to answer any questions you or other members of the committee may have.

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ADDENDUM

NCI's response to the questions specifically raised by the Committee in a letter dated on February 22, 1994.

In response to the request concerning NCI's decision not to follow the November 23, 1993 recommendation of the National Cancer Advisory Board (NCAB) to retain the previous NCI mammography guidelines:

Viewing the NCAB as a valued advisory body, NCI listens carefully to the recommendations made by the NCAB. But while the motion last November "to defer action on recommending any changes" achieved a majority of votes, there were a variety of opinions expressed. In early December, Dr. Paul Calabresi, chairman of the NCAB made the following statement: "I am extremely pleased by the nature and substance of the NCI statement. I think the recommendations are both accurate and appropriate. NCI is a science-based organization and the statement represents an excellent summary of scientific fact."

A long-term member of the NCAB, Dr. Howard Temin, a Nobel laureate who died in February, wrote to Secretary Shalala on December 7, 1993. In his letter he supported the "NCI statement of fact about breast cancer screening that was released last week. I think that the recasting of the National Cancer Institute as a science institute is most appropriate. Health care is much too complicated for us to be involved in without much more study."

More recently, on February 23, the NCAB unanimously (with one abstention) passed a motion as follows: "Inasmuch as cancer research is the primary mission of the National Cancer Institute, the NCAB recommends that the NCI not involve itself independently in the setting of health care policy." Thus, we believe NCI is in substantial alignment with the most recent NCAB motion that, as a general rule, the generation of knowledge and the dissemination of factual information, but not the formulation of guidelines per se, is the highest priority. The latest vote of the NCAB supports the original decision of the NCI to stick to the facts and not attempt to issue a pronouncement where neither clinical trials nor a consensus of the scientific community informs what we do.

Question (i): the benefit of mammography as a method of early detection of breast cancer.

Answer: NCI has judged that nearly thirty years of clinical trials have confirmed that routine mammographic screening of women ages 50 to 59 who have no symptoms of breast cancer will reduce deaths from breast cancer by about one-third. The data currently available from randomized clinical trials for women ages 70 and over are inadequate to judge the effectiveness of mammography. However, late summer of 1990, the NCI and other organizations including the National Institute on Aging, the Health Care Financing Administration, and the University of Massachusetts Medical School sponsored Forum on Breast Cancer in Older Women reviewed the clinical trial results and concluded that screening

of women ages 65-74 and above should be encouraged at regular intervals of approximately every two years, and that screening of women ages 75 and above should also be encouraged if the women's general health and life expectancy are good. The results of the mammography screening trials for women in their forties show that in the first 5 to 7 years after screening begins there is no reduction in mortality from breast cancer that can be attributed to screening. There is an uncertain and, if present, marginal reduction in mortality at about 10 to 12 years. No single trial, nor aggregation of trials, shows a conclusive reduction in breast cancer deaths.

Question

Question (ii): What NCI is proposing to women as a substitution for mammography for early detection.

Answer: First, we have made no change in our position on mammography for women over age 50 and in fact, there is considerable evidence now that mammography is an effective screening tool in this older group which is so heavily affected by breast cancer. Thus, for 80 percent of breast cancer cases, no substantive change in perspective on this issue is in order. We are not recommending for or against screening mammography for women in their 40s. NCI continues to view, as a prudent health practice, annual clinical breast examinations (although randomized clinical trials have not been conducted to prove a reduction of mortality) for women 40 and older and monthly breast self examinations for women over 40. We expect certain risk genes, such as BRCA-1, to be identified in the near future. Thus, in the near future, NCI-generated technology may make it possible to identify certain subsets of younger women, for whom intensive screening and intervention may be appropriate.

Question (iii): NCI's current research activities on alternative screening techniques.

Answer: We anticipate development of new technologies such as digital mammography and magnetic resonance imaging and other new methods which enhance imaging. Studies that test the feasibility of such new technologies will include young women and will have a clear requirement to include minority women. Indeed, this is an unusual time of flux in the science of breast imaging. We are continuing to stimulate the development of innovative methods of imaging the radiographically denser breast tissue of younger women--tissue that can be exceedingly difficult to image with conventional mammography. And we continue to work toward simple screening tests, possibly blood tests, that would pick up molecular evidence of breast cancer or breast cancer susceptibility, and at the same time, might be the basis for new and effective therapies.

Question (iv): How physicians should utilize the new guidelines with their patients.

Answer: In effect, NCI's new fact-statement is now in accord with the position of the U.S. Preventive Services Task Force, which has guided some physicians for several years. One point must be emphasized: we are talking about screening, a process done on large numbers

of women who are free from signs or symptoms of disease. This discussion does not address diagnostic mammography, where a doctor and woman are joined in evaluating symptoms or other indications, such as a lump, pain, or swelling, of a possible malignancy. Evaluation of a woman with symptoms is an entirely situation than screening. In evaluating symptoms, mammography, in conjunction with other diagnostic tools is considered a standard procedure at any age. We also want to stress that when a doctor's clinical judgment and knowledge of a particular patient in concert with the informed wishes of the patient, leads to a decision to recommend mammography (screening or diagnostic), we at NCI would gladly defer to the sanctity of the doctor-patient relationship. Some physicians and their patients may be influenced by the fact that the positive predictive value of screening mammography is comparatively low in young women with no family history but goes up if there are additional risk factors such as a first-degree relative with breast cancer. We would want the patient to be made aware of the facts (including a discussion of the possible negative features, not just the positive features) as they are known about the procedure, but the patient-doctor relationship must be protected and respected. Moreover, we believe that a doctor should carefully listen and determine whether any individuals requesting screening have a suppressed fear or are subtly expressing a concern about their health even if they cannot put it into words. All of us know it is sometimes difficult to raise such issues directly. A doctor should inquire and try to elicit if there is an unspoken factor in the equation. What is sometimes lost in our discussions is the point that mammography should be an adjunct to the practice of medicine, not a replacement.

Question (v): the impact the change in guidelines will have on African-American women given NCI's assessment in a recent publication:

> "However, such is not the case for premenopausal African-American women, whose mortality rate (from breast cancer) has risen by 2.5 percent despite the fact that the incidence rate for this group is generally lower than that for white women...Experts believe that this disparity in mortality rates may be significantly influenced by poverty, lack of access to early detection, and health care."

Answer: From a study of the HIP trial we have reason to believe that mammography is no less and no more effective for African-Americans than it is for white women. In women over age 50, a reduction in deaths from breast cancer was achieved. For African-American women, as for white women, there is a choice to be made about whether or not to have mammography, and they should be informed that on the basis of randomized clinical trials that screening in the age group 40 to 49 has not been found to reduce death and that it holds the possibility of both false negative and false positive results in part due to the difficulty of detecting tumors in the radiographically denser breast tissue of young women. It is especially important to ensure that clinical advances, such as adjuvant chemotherapy after the primary tumor is treated, be made available to minority women. NCI has a number of programs to address the disproportionately high cancer morality rate in African-American women taking into account the effects of poverty, lack of access to early detection--and a lack of adequate technology for early detection--and lack of access to state-of-the-art medical care. But it is

worth stressing that, about all else, real progress against breast cancer in all women--white and African-American-- will depend on a durable commitment to basic cancer research.

Mr. TOWNS. Dr. Broder, the Fletcher report played a pivotal role and formed the scientific basis for the formulation of the guidelines. Do you agree with that, Dr. Broder?

Dr. BRODER. It played one role. I am not going to say whether it was the pivotal role.

Mr. TOWNS. This editorial by Dr. Susan Fletcher, the chair of the workshop. She evaluates the data on her own and concludes that the mammography guidelines for women in their forties should be eliminated. Dr. Fletcher wrote this editorial and issued a press release on this. Two months before the workshop she wrote:

"Groups recommending routine breast cancer screening in women under the age 50 should review their recommendations."

With unanimous consent, I ask that the full text of this editorial and the press release as well be submitted to the record. Dr. Broder, who at NCI recommended Dr. Fletcher to chair the workshop?

[This information can be found in the appendix.]

Dr. BRODER. The recommendation was made on behalf of Dr. Peter Greenwald, who makes those selections. He did so on the basis of the advice of his staff.

Mr. TOWNS. Did Dr. Fletcher write her editorial before or after she was chosen to chair the workshop?

Dr. BRODER. I believe it was before.

Mr. TOWNS. Dr. Broder, all the NCI personnel involved in this workshop told the subcommittee that they didn't see a problem with Dr. Fletcher's objectivity to evaluate the science at the workshop even though she had publicly announced her position on the matter just 2 months before the workshop.

Don't you think that by publishing her editorial, Dr. Fletcher's objectivity to chair the workshop and write the report was compromised? Was this a concern at NCI, especially because of the critical role the workshop and the report was going to have on the guidelines?

Dr. BRODER. No, sir. I believe that on this particular issue, there is a polarization of scientific thought among all parties to an extent that I have personally never seen in my 22 years in the government.

And it is impossible to have individuals participate in a workshop, or at least it would be extremely difficult, if all individuals who participated in a workshop or were invited to write scholarly manuscripts were precluded from doing so on the basis of their prior statements or publications.

In some sense, it is better for Dr. Fletcher to have published her views and let everyone know where she stands, permitting her views to be shot at or objected to in advance under a scholarly format than for her to harbor private views which she doesn't disclose.

Mr. TOWNS. Let me go on talking about this situation here. In addition to questions about Dr. Fletcher, I have a printout of grants that NCI has granted to the other members of the writing committee of the international workshop.

Without objection, I would like to insert this in the record.

[The information follows:]

	INVESTIGATOR	NUMBER	TITLE	INSTITUTION	AWARD	YEAR
CONTRACTS	RIMER, BARBARA	5 N01 CO33022-00	CANCER INFORMATION SERVICE (REGION 06)	DUKE UNIVERSITY	536,238	93
GRANTS	FLETCHER, SUZANNE W	5 R01 CA45022-03	NEW HANOVER BREAST CANCER SCREENING PROG	UNIVERSITY OF NORTH CAROLINA CHAPEL HILL	447,940	89
GRANTS	RIMER, BARBARA K	1 R13 CA57418-01	N.C. BREAST CANCER SUMMIT	DUKE UNIVERSITY	24,187	92
		1 R01 CA59734-01	ENHANCING CANCER CONTROL IN A COMMUNITY	DUKE UNIVERSITY	295,802	93
		1 R01 CA63782-01	INCREASING BREAST SCREENING AMONG NONADH	DUKE UNIVERSITY	353,604	93
GRANTS	SHAPIRO, SAMUEL	1 R01 CA60954-01	CASE CONTROL STUDY OF DMPA AND BREAST CA	BOSTON UNIVERSITY	222,406	93

Mr. TOWNS. I notice here that Dr. Fletcher received $536,000 on one occasion. Then down here a little further, I think she got a little more.

And then Dr. Rimer, who was a part of the writing committee received $1 million in 1993.

Does this funding have anything to do with the workshop's conclusions? Is there any kind of connection here?

Dr. BRODER. No, sir. And if I could elaborate.

Mr. TOWNS. Please do.

Dr. BRODER. Giving an assistance mechanism, a grant in aid, is not viewed as an impediment to someone providing expert scientific advice.

I do not challenge and have respected the debate that has gone on. We have individuals from all disciplines. If that logic were applied, no individual who served or very few individuals who were diagnostic radiologists would be permitted to enter the debate because in some cases there are fee-for-service arrangements.

I would like to say, and I'm grateful to the Chair for the opportunity to say this, I believe that the people who are in this debate, without exception, are people of good will and are of high intellect, but there is polarization. And the polarization cannot be made to go away.

I do not believe that applying for and seeking and obtaining NIH funding through a peer review mechanism disqualifies an individual, and I don't believe that somebody's professional occupation disqualifies an individual.

Mr. TOWNS. My time is expired, but let me just say this. I think credibility is very, very important and, the subcommittee has been asking this question in reference to who recommended Dr. Fletcher, and at no point in time did the name Dr. Greenwald come up in terms of who recommended Dr. Fletcher.

I just wanted to share that with you that the staff has been trying to find——

Dr. BRODER. Dr. Greenwald informed me that he had told staff that that was what he said. But I will certainly remonstrate with him if he did not provide accurate or clear information.

I, unfortunately, was not present at the interviews and so I can't say what happened. But I will certainly remonstrate with staff if they have not been forthcoming and have not shown the appropriate respect and cooperation. But Dr. Greenwald, as head of that division, does have that responsibility.

If I could just say, Mr. Chairman, this is an issue where not only scientists disagree among themselves, but we have examples where scientists, or an individual scientist, may in a short time be a coauthor of publications which appear to say opposing things. So we have individuals themselves disagreeing with their written comments or their public statements in short proximity to the statements. I feel this is an area where there are going to be significant disagreements, and we really have difficulty addressing this issue.

Mr. TOWNS. Let me ask you this, Dr. Broder. How many times in the past has the advisory board ruled one way and you've gone another way?

Dr. BRODER. The advisory board gives advice, but how many times have we not taken their advice?

Mr. TOWNS. Yes. How many times has this happened?

Dr. BRODER. Twice that I'm aware of, and they both ironically happened at the same session. [Laughter.]

Mr. TOWNS. I can sort of understand that, too.

Mr. SCHIFF. Why does that not surprise me?

Dr. BRODER. Well, the recommendation that we couldn't follow was that we received advice to spend money for NRSAS, a certain kind of research fellowship, and to spend it in spite of the fact that we didn't feel that the budget was adequate for that, and we had to ignore their advice.

In addition, I believe the NCAB in a subsequent meeting in effect has endorsed the NCI position. That's my point of view. Even within the context of the original vote, the chair of the NCAB, several days after the action, said that he thought it was a scientifically valid and excellent point of view. I am paraphrasing, but I can provide the exact written verbatim concept. Howard Temin, a nobel laureate who served on the board, wrote a letter to Dr. Shalala that he endorsed the view. So what I am saying is, what the NCAB did or said is not as simple as it may be being portrayed.

Mr. TOWNS. Let me just say this to you. You know, I come from New York, which has, as you know—a lot of teaching hospitals and the scientific community is very strong there as well.

I've taken it upon myself to just talk to physicians who have an interest in mammography screening or have information they could share with us.

And in every instance they have said they could not see how you could change the guidelines with unanswered questions. They told me that they couldn't understand why if you lacked the information, how you could move forward. And this is something that was being said by everybody.

So I just want to share with you, the general feeling of people who are involved in the scientific community. I'm talking about Rockefeller—I mean everywhere I've talked to people, everywhere I've gone, I've made a point to raise this question with the physicians.

Dr. BRODER. I hear you.

Mr. TOWNS. At this time, I would like to yield to the ranking member of the subcommittee who has been waiting very patiently here. And don't turn on the clock on him. I mean he has been waiting too patiently.

Dr. BRODER. I'm here at your disposal, so don't rush on my account.

Mr. SCHIFF. Thank you for that. Dr. Broder, I want to first say, I want to thank you for your personal commitment to see that any problems between—that may exist between your staff and the subcommittee staff in terms of obtaining information will be resolved.

It's my experience that agencies all too often regard the Congress as some kind of pest when we look closely at what they're doing. And I used to work for an agency, albeit a State agency, so I can understand that feeling, but the fact has to be remembered that——

Dr. BRODER. Sir, you are the lawful expression of the people, and I understand that.

Mr. SCHIFF. Well, and on a more practical level, every dollar that goes to any agency is raised through our authority from the hard-earned income of the American people. And they expect us to look after what's going on with it. So I'm expressing my appreciation, you know, at your expression of cooperation.

What I would like to do is go back for a moment. It's my understanding that for several years, ending in December 1993, the National Cancer Institute itself recommended mammography for women under the age of 50 I believe on a—once every 2-year basis. Is that right?

Dr. BRODER. It did. There were guidelines that were published in 1987, approximately 1987, and then other information came along. And that's when that particular point of view was codified.

Mr. SCHIFF. All right. So for how long did the National Cancer Institute recommend mammography for women between the ages of 40 and 49, regardless of how often that mammography might take place?

Dr. BRODER. Approximately 6 years.

Mr. SCHIFF. And was it in December 1993 that the National Cancer Institute revised that guideline to not recommend mammography between the ages of 40 and 49?

Dr. BRODER. Two things happened at that point. The policy of the National Cancer Institute indicated that in the face of this incredibly controversial issue it was best to attempt to stick to the facts and not to convey the impression that we were making a pronouncement that would have more authority than we could support.

Mr. SCHIFF. Well, my question was just, what's the date?

Dr. BRODER. December 1993.

Mr. SCHIFF. All right, you've perhaps anticipated the next question of why. And your answer was that you want to have guidelines that are based on facts, essentially, right?

Dr. BRODER. We want to have either a consensus or clinical trials, particularly when we appear to be opposing another government-sponsored agency, in this case the U.S. Preventive Services Task Force.

In that case, when we are opposing another government agency, for me to stand up, in effect, de facto, to another government agency which resides within the Public Health Service, then I need to have either a consensus of the scientific community or I need to have a clinical trials process. If we lack both, then we have to reexamine what it is that we are doing and what we are saying.

Mr. SCHIFF. So you're saying, for 6 years, the National Cancer Institute did not have a valid basis for recommending mammography between the ages of 40 and 49, which was your recommendation?

Dr. BRODER. No. If I could explain. One of the points that I think is very important, which came out and which I want to stress again, is that these studies inherently take an extremely long period of time. It takes roughly 10 years, approximately, to gather the relevant data just to do the study.

For the HIP study, which is the gold standard of all of these studies, and ironically, by the way, which has achieved the best result—or at least from my point of view, the best result that has

been achieved to date as a practical matter, a one-third reduction in death rate—data were still being gathered at approximately 17 years.

This poses a special challenge, and Mr. Towns, you gave us that challenge. The challenge is, what do we do with information on the basis of a clinical trial? Do we just wait like people in long white coats and detach ourselves, or do we attempt to make best information we can as we know it?

And I believe in 1987, what they did then was right. There was still a clinical trial, a randomized trial that was being done that still might come in. There were inferential data.

And another important point. In 1987, it appeared that we had a greater consensus. Even then, however, there were some individuals and some organizations who opposed recommending screening between 40 and 50.

But 80 percent of what was done in 1987 still stands because approximately 80 percent of the cases of breast cancer are over age 50. We were right to do what we did. But in the absence of——

Mr. SCHIFF. Were in 1987?

Dr. BRODER. Yes. Yes, we were right. But what I'm saying is we cannot rigidly adhere and ignore new facts as they come in——

Mr. SCHIFF. So what are the new facts that have come in that caused the National Cancer Institute to change the guideline that had been in existence for——

Dr. BRODER. The Canadian randomized trial did not show a positive result. There are criticisms of that study. However, the investigators have published in the Annals of Internal Medicine what I consider to be point-by-point rebuttals of the criticism. So we did not have a study that came out in a positive direction. A meta-analysis of available studies done worldwide, including the original HIP study, did not show a statistically significant benefit.

If we were able to get a consensus point of view, then we might have been able to say OK, even without clinical trials, we'll go ahead. But the difficulty that we have is that mammography is a procedure. It has effects on women. It does expose them to ionizing radiation. It has issues.

And if a woman were to ask us, on what basis do you make your guidelines; why are you telling us to get mammography between the ages of 40 and 50, we need to be able to say something other than because we say so.

And some women's groups have actually written to us objecting to our guidelines between 40 and 50, and their eloquent letters have been provided to the subcommittee. They've done extensive analysis on this point. It's hard for us to say to them, well, OK, this is what we think. We do not object to mammography between 40 and 50. We are not for it or against it as an institute.

What we are saying is that women should be told the facts. They should be told the facts. They should be given an informed consent, if you will. They should know that the positive predictive value of mammography is lower in that group, and they should know that there are false positives and false negatives.

Mr. SCHIFF. But the point I'm getting at is, for 6 years you did have a position on the issue of between 40 and 49.

Dr. BRODER. Yes, that's correct.

Mr. SCHIFF. And you were in favor of it. And what I'm concentrating on is the reasons for the change. And you cited, for example, a Canadian study.

Dr. BRODER. That's correct.

Mr. SCHIFF. All right. You know—I won't belabor this, but you're aware of the criticisms of the Canadian study.

Dr. BRODER. I'm aware of both the criticisms and the rebuttal.

Mr. SCHIFF. All right. Let me ask you this question. Of the individuals who are the subject of the Canadian study, that is, in Canada, what is the racial makeup and ethnic makeup of the individuals who participated in the Canadian study, and how would it compare to the average racial, ethnic makeup in the United States?

Dr. BRODER. They were disproportionately white. There was inadequate representation of African American and other minorities.

Mr. SCHIFF. And you're well aware, because you say it in your statement, that the mortality among African American women is greater in breast cancer than among Caucasian women?

Dr. BRODER. Absolutely.

Mr. SCHIFF. All right. Nevertheless, you base changing a 6-year-old standard and guideline on a study that had a disproportionate number of Caucasian women in it compared with the standard population of the United States?

Dr. BRODER. That's correct in the meta-analysis of all of the international studies. The HIP study, however, had an over-representation of African American women at 17 percent.

Mr. SCHIFF. But that's the study that existed in 1987 upon which the guideline was based that said——

Dr. BRODER. That's correct, but even looking at that study, if you just focus between 40 and 50, there was not enough of a basis one way or the other to recommend mammography. And most of the effect in that study seemed to be driven by women over 50. And even under the age of 50, a proportion of the tumors that were found in that study involved clinical exam.

Please, I ask you to recall that some of the times when we talk about mammography, we omit the fact that some of the studies, and in fact the process of doing it, involves both clinical breast exam and mammography. In some cases, we cannot tease them apart. And so what I'm saying is, even in the HIP study, I cannot tell you 100 percent that mammography is the driving force—all I know is that the combination of the two is what we're talking about.

Mr. SCHIFF. But let's talk about one more thing. Let's talk about consensus because you have raised the issue of consensus.

The chairman touched on it, but I want to go back. You have your own National Cancer Advisory Board to advise the National Cancer Institute. Is that right?

Dr. BRODER. That's correct.

Mr. SCHIFF. And according to my information, they had a formal vote on whether the NCI should change this standard guideline, as you've changed it, and they voted 14 to 1 not to make this change.

Dr. BRODER. To defer. They didn't say don't change. They said defer.

Mr. SCHIFF. What do you mean defer?

Dr. BRODER. It wasn't clear what the committee meant. My understanding of the motion was that they wanted to defer or not do something at this time.

Mr. SCHIFF. Well, defer it means don't do it, doesn't it? [Laughter.]

Dr. BRODER. Not necessarily. And the reason—I'm not trying to spar with you or do debates—the reason I feel I can say that is the chair within a few days said he was very happy—the chair of the NCAB, the same organization that had that vote—that he was very happy with what was done. He thought it was scientifically correct and the right thing to do. And a nobel-laureate-winning member of the NCAB, Dr. Howard Temin, one of the most brilliant people in our program, strongly supported it.

Mr. SCHIFF. Have they had a new vote in which the advisory board has officially endorsed this change?

Dr. BRODER. They have had a vote which in my opinion ratifies what we are doing. They had a vote at the February NCAB meeting which asked the NCI not to develop policy guidelines independently.

From my point of view, that means that if another government agency takes a point of view and we don't have the facts or the consensus to oppose them, we must yield to the other government agency, particularly when it has been given a mandate to do the very thing that we're talking about.

Mr. SCHIFF. Well, since they are your advisory group—are they specifically for the National Cancer Institute?

Dr. BRODER. Yes, they are.

Mr. SCHIFF. All right. Do you have it within your authority to request that they convene and have a vote specifically up or down whether they support this change or not? Can you do that?

Dr. BRODER. I could discuss it with the chair. I don't have the capacity to compel them to do anything.

Mr. SCHIFF. Well, can you request that they have a meeting and have a formal vote on whether they approve this change in the guideline or not? Can you make that request to them?

Dr. BRODER. I can. I can ask the chair. I cannot guarantee that they will do that.

Mr. SCHIFF. Well, are you willing to ask the chair?

Dr. BRODER. Yes, I will. If you ask that I do that, I will.

Mr. SCHIFF. I'm asking that you do so.

Dr. BRODER. It will be done.

Mr. SCHIFF. All right. Now, a couple of other groups. You referred to——

Dr. BRODER. But if I could please say?

Mr. SCHIFF. Yes.

Dr. BRODER. The President's Cancer Panel is another organization, in my opinion, of equal or potentially greater rank, headed by Dr. Harold Freeman. He has the authority—by statute—to do something that I'm not allowed to do and no other government official is allowed to do.

He is given permission to call the President directly. He can oppose anything that goes on.

And within the rubric of the President's Cancer Panel, there was a special commission under the overall aegis of Dr. Freeman, but

chaired by Nancy Brinker, with two diagnostic radiologists, including a former president of the American Cancer Society and the head of an important committee of the American College of Radiology.

And they came out with recommendations published in the fall of 1993 that data regarding the benefit from mammography screening in women ages 40 to 49, in effect, are inconclusive. That's their word. And they discussed that this could possibly be due to limitations in the study design or implementation. It is very difficult for us as an agency to take conflicting advice.

Mr. SCHIFF. Have they endorsed your change?

Dr. BRODER. The commission charter has expired, and they no longer exist.

Mr. SCHIFF. They no longer—I mean a commission on cancer no longer exists?

Dr. BRODER. This is a special commission on breast cancer. It tended to give an overall strategic philosophy of what the Institute should be doing. And in the spirit of the executive order issued by President Clinton to deactivate the Federal advisory committees whose function has ended, the term of this was essentially to be ended upon publication of its brochure. It is ended.

Mr. SCHIFF. Did they—before they terminated, did they express a specific recommendation as to what the guidelines should be or not be?

Dr. BRODER. No, but we did have correspondence from them to suggest that they were very happy with the report. And this is a letter from Dr. Dodd saying that "I am in concurrence with all of its contents."

Mr. SCHIFF. Didn't they recommend that further studies be done before the guidelines be changed?

Dr. BRODER. Yes, there was a sentiment to do further studies. But my position is that that aspect is tantamount to delaying forever.

In other words, one of the questions one has to ask, if you will only act when a study is positive, then in effect you don't need to do the study. And there may be certain situations when that's true, but in this type of a situation when we have intense polarization, we cannot pronounce a knowledge base that doesn't exist.

We were certainly looking to new ways of doing studies. But please if I could just add, the current views of mammography are widely held by all parties. They may have opposing views, but doctors and women all have strongly held views.

One question that one has to ask is, can you even do a randomized clinical trial? This is an important issue. We will look into it, but many women will object to having a computer essentially tell them they will either get mammography or not, and then they have a moral obligation to adhere to what the computer has said.

In addition, it is unthinkable, and we will never do a study in a target African American population or a Hispanic population or an underserved population or prisoners or anybody else who might be considered an underserved or targeted group, we will not do a study on such a population that we would be unwilling to do in the population at large.

So this leads us to very strong difficulties. We think we may get additional answers. We may be able to say more on the basis of molecular biology and facts that are coming in very quickly—the gene for certain forms of breast cancer called BRCA–1 is nearly cloned and identified—and to develop additional indices of who should get mammography between 40 and 50, or maybe even younger than that.

We are looking at DDT and DDE exposures. We have a separate study in Triana, in the Tennessee River Valley in Alabama, in which minority women were exposed to very high levels of DDT and DDE by unlawful dumping into a river site. We are looking to see whether these studies will give us a risk factor assessment.

But I might also state one other fact. There may be certain genes that predispose certain women to risk from x rays—and we are studying this issue—so that a woman should avoid ionizing radiation.

There are ataxia-telangiectasia genes which are present in the population, and there are data published to suggest that these women have a higher incidence of breast cancer and they are susceptible to ionizing radiation.

Mr. SCHIFF. But I would like to come back to the question of consensus on this issue, the issue of changing the guidelines. You made a reference to the U.S. Public Health Service, the Preventive——

Dr. BRODER. The U.S. Preventive Services Task Force.

Mr. SCHIFF. Right, of the U.S. Public Health Service. They are in disagreement with the changing of the guidelines. Is that right?

Dr. BRODER. No. We are now in alignment with them.

Mr. SCHIFF. They recommend the same thing?

Dr. BRODER. They disagreed with our 1987 point of view.

Mr. SCHIFF. I see.

Dr. BRODER. That's the point. We went ahead in opposition. They came in in the late 1980's with a recommendation, based on a lot of work, that said basically, focus mammography on women over 50. That was where they came out.

They did not endorse a policy of mammography between 40 and 50. We went ahead anyway. My position is now we have lost a consensus, we do not have a consensus, and we do not have the clinical trials. It becomes very difficult for me to argue with others who oppose what we are doing by simply saying, "I said so; this is the way it is."

Mr. SCHIFF. Well, what is the recommendation of the National Cancer Society?

Dr. BRODER. The American Cancer Society?

Mr. SCHIFF. Right, the American Cancer Society, I'm sorry.

Dr. BRODER. I would like to thank you for that question. I believe there is considerably more agreement between the National Cancer Institute and the American Cancer Society than is currently being portrayed. I believe there are a number of areas of agreement.

We will be having a workshop that will be held within approximately a month that will allow us to get together. We want a consensus. I would like the subcommittee to know that I did not like the way the clinical trials results came out—not from the standpoint of a scientific issue. I did not want this answer; I was not

looking for this answer. I was not looking for a polarization among scientists, many of whom are much smarter than me. And I was not looking for a situation where the clinical trials data did not back up what we were doing in one age group, but did in another.

Mr. SCHIFF. Well, you know, Dr. Broder, I have to say I think I'm asking short questions, and I'm not able to find the answers in your somewhat lengthier answer.

My question is, does the American Cancer Society have a recommendation on mammography between the ages of——

Dr. BRODER. Yes, they do.

Mr. SCHIFF. And what is that recommendation?

Dr. BRODER. Their recommendation essentially is our old guideline, which is that mammography be done—well, in the interest of brevity, I won't recite it here.

Mr. SCHIFF. All right. But it's your old guideline?

Dr. BRODER. It in effect is the old guideline.

Mr. SCHIFF. The one you changed?

Dr. BRODER. The guideline which has been supplemented with a fact statement.

Mr. SCHIFF. All right. OK, thank you, Dr. Broder. I yield back.

Mr. TOWNS. At this time, I yield to Congressman Portman.

Mr. PORTMAN. Thank you, Mr. Chairman. Thank you for holding this hearing as a followup to the full committee hearings on this subject.

Dr. Broder, as is the case with many Americans, I think a lot of people in this room, I have a personal connection with this issue. My mother-in-law died of breast cancer at age 50. She is one of those thousands of women who should have had a mammography screening and she didn't in her forties. So I have again a personal interest and connection that many in this room share.

Dr. BRODER. I share your personal and intimate connection on this point, I can assure you of that.

Mr. PORTMAN. My questions really are followups to Mr. Schiff's questions and the chairman's questions, and really get to the future.

It seems to me that we have a situation where at the end of the year last year there were 12 prestigious groups, including the American Cancer Society, which opposed changing the screening guidelines.

We have a situation where your own NCAB opposed it. I think there's another group that reports to you, called the Board of Scientific Councilors, that opposed it as well. Is that correct?

Dr. BRODER. No, that is not correct. The Division of Cancer Prevention and Control Board of Scientific Counselors endorsed recommending the position of over 50, but did not recommend a general guideline or utilization of screening mammography between 40 and 50. That's another example of the polarization of advice that we received.

Mr. PORTMAN. Yes. We have a situation where we have a significant number of medical experts who were on one side of the issue, you all came down on the other side of the issue. My question is really in a situation like this, do you have any plans to review the Canadian and European studies that you've done and to really set

into place a process to review your recommendation to see whether it's the correct recommendation?

You talked a moment ago about the difficulty of conducting future studies. On the other hand, you have based your decision on studies already. It seems to me it would be inconsistent not to proceed with other studies that are perhaps more representative of this population.

Dr. BRODER. We will. We are doing so now. We are looking for new avenues of expanding clinical trials already launched, particularly in those countries where the patients and the doctors feel it is ethical to allow a computer to do the randomization.

We will explore to see whether women of this country, white and African American and Hispanic, would be willing to agree to a computer randomization, because it won't help us if they say, OK, I'll do a randomization, but I'll go ahead and do mammography no matter which side I get randomized. You'll get the wrong answer. So we have to see whether it is feasible to do such a study in the United States.

We will also look to see whether there are biochemical or genetic or other markers which will identify those individuals who should be screened. Even the simple fact of asking a woman does she have a first-degree relative who has had breast cancer will increase the positive predictive value of the test.

So there may be some simple areas where we could have common ground. We are working on this point. We understand the urgency of the issue.

Mr. PORTMAN. And what is your timeframe in terms of beginning to initiate new studies or in terms of having an independent review of your recommendations?

Dr. BRODER. The United Kingdom study has already been launched, and it will contain something like 70,000 individuals for the screen, with a 2 to 1——

Mr. PORTMAN. Total——

Dr. BRODER. Yes, 70,000 will be screened, but the total population will be 200,000 because there's a 2 to 1 randomization. We have already contacted them. We will look for ways of supplementing or dealing or maybe expanding the studies.

I personally would think that we should focus a great deal of attention on certain markers, biochemical or risk factor markers, that might identify some individuals who are particularly suitable for screening and for whom the screening may be able to be particularly beneficial.

Mr. PORTMAN. And does NCI itself have a deadline to review the policy? As an institution have you set a timeframe within which you will review it?

Dr. BRODER. No, we have not set a timeframe.

Mr. PORTMAN. Would that make sense? Is that something you would recommend?

Dr. BRODER. No. I would defer to the scientific community to tell us a timeframe. It is similar to the Long Island study, that Mr. Towns is aware of, where we were given a 36 month timeframe to do a study in two counties on Long Island having to do with environmental carcinogenesis, and that was written into the statute.

I asked and appealed to Mr. Waxman, the chairman, and I believe the members of the subcommittee were united behind him, to give us more time so that we could do the study correctly. We will give an interim report in 36 months, but we asked for approximately 5 years to do the study.

So the exact time will be driven by the scientific peer review community. We're not wasting time, though.

Mr. PORTMAN. Dr. Broder, my red light is on. Let me just say that it's my opinion that when there are so many unanswered questions that guidelines ought to be adhered to are ones that are more cautious, rather than less. And I would hope that the NCI will, in fact, review its recommendation with haste.

Mr. TOWNS. Thank you very much. Let me start the second round. I noticed in your response to Congressman Schiff that you indicated that the chairman of the advisory board changed his opinion, or changed his vote. Do you mean that when that happened that it went from 14 to 1 to 13 to 2?

Dr. BRODER. No. What I mean to say is that there were multiple interpretations of what the Board meant, and even the members of the Board who voted had different opinions about what they were voting on.

Mr. TOWNS. I just want to say that people feel that since NCI has never overruled the advisory board before and that it occurred at this point in time, appears to be a cost saving action. And I just want to let you know that is what's circulating out there.

And while I'm on that note, let me ask you a question, Dr. Broder. Did you have any discussions or any type of meetings, correspondence or contact with anyone in the administration involved in health care reform regarding your mammography guidelines? Do you know of anyone at NCI who had discussions, correspondence or meetings with the administration on health care reform?

Dr. BRODER. I have personally had discussions with Dr. Phelip; and, in fact, I have to see him in 1 hour in anticipation of testimony tomorrow before Senator Mikulski. So yes, I'm in very frequent contact with Dr. Lee. I'm also in very frequent contact with Dr. Devra Davis, who is an individual in the Office of the Assistant Secretary who has a great deal of knowledge and familiarity of these issues. She was passionately opposed to our 1987 guidelines.

Mr. TOWNS. Did they pressure you that if you'd change the guidelines, they would be able to save money, bring health care reform under control in terms of cost factors, and that the best time to do this would be now? Did this kind of discussion take place?

Dr. BRODER. No, sir. The process had been launched before President Clinton was elected, and many of the steps that were taken leading to the workshop occurred in 1992. This was not done as part of an expedience for health care reform. There is no one who could force me to do something on that basis.

Mr. TOWNS. Let me point out something that was in the New York Times just recently. It says—based on cost estimates from the New York Times—the cost of—screening all women in the United States between the ages of 40 and 49 amounts to $8,000 per cancer, as opposed to $84,000 to treat this same breast cancer in a later stage. Are we rationing women's health to save costs for a health care plan, costs that don't even make sense?

Could you respond to that?

Dr. BRODER. Yes, I will. That's not one of the factors that we take into account. One of the things that I want to clarify is there is an analogous situation for prostate cancer. A PSA test is available, and some use it for screening.

We at the NCI have specifically avoided recommending it for use as a public health screening measure. We have a very large clinical trial, called the PLCO trial, which has been launched and which we hope will answer the question whether it really does reduce the death and suffering due to prostate cancer in men. That is a very analogous situation.

We are not recommending—you will find no correspondence or no statements, at least from anybody that I know at the Cancer Institute, that is recommending—PSA as a routine screening procedure for asymptomatic individuals. We want to know the facts.

And if the studies come out that PSA reduces mortality then that's fine, we'll make those facts as widely known as we can. If it fails to reduce mortality, or doesn't seem to have the effects that we're looking for, we have to stick to the facts. We don't object if others wish to take another point of view.

Mr. TOWNS. Let me just say that I'm hoping that there is not this cost saving mood present at NCI, because I think if it does exist, then in the long run we'll find out we're hustling backwards.

Dr. Broder, what can women in their forties do for early detection? The same trials that showed benefits for mammography also utilize clinical breast examinations. Wouldn't you conclude from these that clinical breast examinations show no benefit?

Dr. BRODER. That's correct. I cannot say that there is a statistically significant reduction in the death rate attributed to CBE, clinical breast examination between the ages of 40 and 50. Over 50——

Mr. TOWNS. So what would you advise?

Dr. BRODER. I can tell you what we are advising. We think that this should be individualized to the woman. We think the average woman in this country is very intellectually gifted. We have done focus groups where women have told us they want to know the facts, they don't want to have things hidden from them. If we make a recommendation they want to know on what basis. If a test is either good or bad, they want to know. And then they want to have the right to make the decision themselves, but armed with the facts.

I think we're consistent with that spirit, and therefore, we think individual women will need to discuss the pros and cons of mammography with a knowledgeable health care provider. And then we're very comfortable, whatever the decision is. But the facts should be given to a woman.

Mr. TOWNS. I'm going to leave you on this question. I have here a quote from the September 24, 1993, cancer letter referred to on the video. Did you, in fact, make this statement: "What I would do as an individual is recommend annual mammograms. But I can't recommend it to the public because I don't have the facts."

Dr. Broder, explain to me how you can reconcile holding your own patients to a higher standard than the rest of American

women. Are you saying what is good for American women is not good enough for your patients?

Dr. BRODER. That statement has been widely misunderstood. And the point that I wanted to make with that statement—thank you for the opportunity to clarify it—is that we can't make policy, as a central government agency, to tell doctors and individual women throughout the country, what to do as though we're acting as individual doctors.

My point is exactly that what you do as an individual doctor with an individual patient is one thing, and that's fine. But no one should tell women they should get mammography because we know, because it's proven that it's going to save their lives. Because it hasn't been so. They have to give the pros and cons. And other facts should be made available.

Dr. Sickles, who coauthored a paper with Dr. Kopans—who I'm sure will give more comment on this—coauthored yet another paper in very close approximation, which essentially concluded that if a woman doesn't have a family history, mammography may not be the best way to go until she is over 50.

In addition, they want women to be informed that in women who are younger than 50, that for every 1,000 women who undergo a screening mammography, about 50 will require further diagnostic procedures. And of these women, one is likely to have invasive breast cancer and one is likely to have DCIS, which is a form of in situ cancer, not invasive. So they want those facts to go out so women should know.

Mr. SCHIFF. Will the chairman yield?

Mr. TOWNS. I'd be delighted to yield.

Mr. SCHIFF. I thank the Chair. Dr. Broder, that brings up an interesting question. As an oncologist yourself, if you were in private practice right now, you had a practice in oncology—I'd like to ask: For your women patients between the ages of 40 and 49, would you recommend mammography?

Dr. BRODER. I can't answer that question without talking to the patient. That's what I said in my opening statement. I think that mammography, in part, has been—especially for women between 40 and 50—automated, so to speak, and I don't necessarily object to that one way or the other.

What I'm asking is that mammography be encompassed within the practice of medicine; that it extend the practice of medicine, not replace it. The individual doctor has to know the individual patient, has to know things about her. And the individual patient should know the doctor. And if the doctor and the patient, knowing all the facts, understand the issues and know the pros and cons then that's fine. I think it would be wrong to make a woman frightened or to have her life consumed with mammography without the factual basis on this point.

In addition, I feel it is wrong to have typical videos of mammography that show very young women who are in their thirties, because the typical woman who has breast cancer—actually, the median age is 63, but 80 percent of the cases are over 50. If you're going to have mammography information you should focus it on the kinds of women where we know the facts and who are the predominate cases.

Incidentally, we did do a video with Phylicia Rashad to attempt to reach younger women. I just wanted to clarify that point, and I appreciate the opportunity for saying that.

Mr. SCHIFF. But therefore, you're saying you would or would not? In your practice would it be standard to recommend mammography even once every 2 years?

Dr. BRODER. No, it would be an individual decision. And I would adhere very strongly to some of the recommendations that were published and discussed at one of our meetings, the "Positive Predictive Value of Screening Mammography." The first author was Kerlikowske, with Dr. Edward Sickles and others, and the paper was published in the Journal of the Medical Association. I would try to adopt their recommendation, which is basically that mammography should be predominantly focused on individuals who are over the age of 50.

And I think that where you are going to look for individuals below the age of 50, you should look for specific additional factors that might tip the balance one way or the other.

We may have the privilege of reporting to the Congress—I can't promise you—within 6 months that we have cloned and sequenced the BRCA–1 gene, which we've been searching for, which is associated with very young women, often with bilateral disease who die of breast cancer at a younger age. We may be able to target certain molecular factors that will give us knowledge, as opposed to a debate over controversy.

That, by the way, is the practical suggestion which Dr. Sickles gave. He said, "My practical suggestion is that we emphasize the need to correct the severe"—and in the United States it is severe underutilization of screening among women who are aged 50 to 64.

Mr. SCHIFF. But I think that begs the question. No one disagrees with that focus. Indeed, the guideline from 1987 had a less frequent mammography recommendation than for women older, 50 and older, as I recall.

Dr. BRODER. It had 1 to 2 years because that was an attempt to reach a compromise. There were some who have advocated every year, and even at that time thought that 1 to 2 years was improper.

Mr. SCHIFF. I think we can accept that there ought to be a focus on women who are 50 and older, but I think the issue then goes to going from a recommendation for mammography for women who are 40 to 49, to no recommendation. And I think that's the issue.

But you answered my question if you were in private practice, and I appreciate that. I yield back, Mr. Chairman.

Mr. TOWNS. Thank you very much. I think that you hit upon the real problem. And I understand what you're saying, Dr. Broder, but then at the same time I have problems when you say that women will be able to take the facts and make a decision based on the information, because there is a lot of confusion out there. What information? I mean, that's the problem.

Dr. BRODER. But there would be confusion no matter what. Mr. Towns, I appreciate the question you're asking. I want you to know that I think about it day and night. But by the same token, even under the old guidelines there were women who frequently would write in or call in and say, "Why did you make these guidelines?"

You have shown two TV shows that speak to one issue. But at the same year when we had those guidelines there were periodic TV shows that said, "The NCI is all wrong. It doesn't have any data." We have had debates on this point.

So my position is women are going to hear information and get information. I have confidence in the average woman in this country. She wants to know the facts. I can't make the breast cancer situation better by not sticking to the facts as I know them.

Mr. TOWNS. No, but when you have the American Cancer Society saying one thing, the National Medical Association saying one thing, everybody else saying one thing——

Dr. BRODER. And the American College of Physicians saying something else——

Mr. TOWNS [continuing]. And you saying something——

Dr. BRODER. Members of the American College of Physicians are the primary doctors for most grownups in this country and they don't adhere to the position of doing mammography between the ages of 40 and 50.

Mr. TOWNS. Let me ask my question this way, because you have a tendency to twist it. So let me ask it this way.

Dr. BRODER. I apologize.

Mr. TOWNS. Would you say that there is more support on the side that says that we should not change the guidelines than on the side that says we should change it? That requires a yes or a no.

Dr. BRODER. I would say that they're equally balanced.

Mr. TOWNS. I would say, doctor, that you need to do some more research. Because even if you took a poll right in this room now you'd find that almost everybody in here would say that we should not change it. Because, doctor, you're talking about saving lives. That's what we're talking about. And of course, when I talk to people that are involved in the field this is what they're talking about. And the only way you can do it is early detection.

I think that you agree that when we look at this chart, which shows mammography can pick up the cancer when it's the size of a raisin, but if a woman skips mammography, her breast cancer will be picked up when it's the size of a golf ball, the chances of survival are better when the cancer is found in its smaller stage. I mean, screenings just make sense. And everybody says that.

Dr. BRODER. Excuse me, may I comment?

Mr. TOWNS. I'd be delighted for you to comment.

Dr. BRODER. With no disrespect, I don't want to debate, because I understand what you are doing. I understand and respect what you're doing, and we're trying to address it. And I understand that I may have a tendency to look flip, or sound flip, or to debate. So I don't wish to do that if it is not productive.

But I do have a response to that chart which I have seen.

Mr. TOWNS. I'd like to hear your response.

Dr. BRODER. And that is that we understand and accept the principle that early detection frequently makes a difference in certain cancers. And where we know that that's the case, either by clinical trials or a consensus, we certainly act. We need one or the other.

But there are some situations where we simply don't know in some women. I don't wish my words to be misunderstood. But in

some women their fate is determined at an early point. Women very seldom die of primary tumors. This is a misconception. The reason why the most overwhelming majority of women die is because they have microscopic spread of their cancer cells at an early point in their disease. There may not necessarily be a linear relationship between the size of the tumor and its ability to spread independently. There may be a different relationship between that spread in women over 50 or under 50. And I cannot tell you that that's a fact.

But there are certain things that we just have to stick to the facts as best as we can; continuing to generate knowledge so that we won't have to have these debates and we'll have knowledge, and that we will have the answers. It's the same situation for PSA. Applying the algorithm that you've just given us, we should be advocating for PSA testing.

Mr. TOWNS. Dr. Broder, I'm going to yield to my colleague. I think you need to understand whether you like it or not, you're our National Cancer Institute and women are looking to you to tell them whether they should or should not have mammograms. They're looking to you for this. I mean, you are our leader on this. You are the ones that set the tone.

And while we're involved talking about implementing a national health plan, I think it's important to make certain that we get a plan that's going to help in terms of saving lives. And I feel uncomfortable with NCI's recent actions; we're moving forward with health care reform and at the same time retrenching from something that we know benefits women.

I just want to share this with you, if you're not aware of it, that people feel that this is just a cost saving measure, that as we reform health care to be able to save some dollars. But in the long run I think that we'll find that we will not be able to save dollars by rationing care; in fact, it's going to cost us even more. So I just want you to think about that as you move forward.

And also I want to share with you that this is a feeling among a lot of members of this body, especially the female members along with a lot of the male members. They feel that this is a cost saving measure.

And I don't know whether you were here earlier today when we heard from several female Members of Congress, testifying on their views and their feelings about the revision of the guidelines. The women's caucus is united. I just want to let you know that there are some problems here, and if you've not been made aware of it I just want to share it with you.

And I yield back to the Congressman from New Mexico, the ranking member, Mr. Schiff.

Mr. SCHIFF. Well, Mr. Chairman, with respect to the sides of the aisle, I left it for you to raise the issue. It may well be a total coincidence, Dr. Broder, but the fact of the matter is that the change in this guideline that we've been talking about here today coincides almost exactly with the issue of what would the administration's proposed health care plan cost.

And issues of cost, of course, is what you provide and why you should provide it. And I think you should be aware that even beyond that, any kind of targeting of expenditures, whether it's the

administration's or someone else's, raise this issue inherently. And I said, maybe it's a coincidence, but you have found yourself, as I'm sure you've gathered by now, if not before now, in the middle of that debate.

If you wish to respond on that I'd be glad to yield the rest of my time to you to do so.

Dr. BRODER. Sir, at the rate that I talk you couldn't give me enough time, so I want to be brief.

I am going to see Dr. Lee in 45 minutes. And I promise you that I will convey the concerns that you have expressed to him personally. But I want to reassure you that this process was our best attempt to stick to the facts and to avoid a situation where we had individuals appearing to argue without there being some basis for developing common ground.

I would hope that I have enough good will with this committee that you might be willing to allow us a process of attempting to seek a consensus where that is possible. We are meeting frequently with the American Cancer Society. They have spoken. I forced Dr. Sondik out of bed one night and made him make sure that in subsequent conversations that a number of issues were brought up.

We will try to reach a consensus where it's possible. And there is a lot more agreement than disagreement, or that appears to be the case. But we are still confronted with a situation where sometimes science changes whether you're talking about science in larger trials or whether you talk about individual doctors doing experiments with drugs in the phase one setting. And if they don't listen to the facts as they're coming in and allow for adjustment of those facts, and simply stick to something, then I don't know what compass we will use to guide us. And that's painful.

Many of the issues for mammography—I understand fully well the symbolism of mammography—but many of them have to do with the fact of providing an entry for women into the health care system. The mammogram was an efficient way to get women in, not only for mammography, and breast cancer issues, but for the whole health care system.

Many of the things that are done to underserved and poor people in this country are disgraceful. And mammography was an efficient way of bringing people into the medical care delivery system. Well, we have health care reform for that, so presumably, women will not be denied access to the medical system. No one will have economics drive what they get or what they don't get.

But we have to stick to the facts particularly when we don't have a consensus, and when we have brilliant people on both sides giving us opposing advice.

Mr. SCHIFF. Let me just say in conclusion I think you have focused the issue. I think that we would all have to agree that we don't have all the answers, and in the scientific community, as well as in other communities, there is an honest difference of opinion.

I think we would have to further agree that there has to be a sound basis for recommendations that come from a prestigious institute such as the NCI that you represent here today. The issue whether there is sufficient consensus, even though there may be disagreement among individuals—whether there is sufficient consensus to justify the original proposals and guidelines that went

into effect in 1987; or whether the consensus goes the other way and would support changing that.

And you see we have another panel following yourself here in just a couple of moments, individuals associated in this issue with many also prestigious organizations. And to me that's the key question I'm going to bring up with them.

Thank you again, Dr. Broder.

Dr. BRODER. Thank you for the privilege of being here.

Mr. TOWNS. Thank you. And keep in mind Dr. Broder, we're not going to go away.

Mr. SCHIFF. I didn't get 88 percent of the vote.

Dr. BRODER. Sir, I don't wish you to go away.

Mr. TOWNS. Thank you very much. I'd like to call our final panel. Dr. Katherine Alley, Dr. Charles Smart, Dr. Daniel Kopans, Dr. Kathleen Cantwell, Dr. Dava Gerard. Since this is an investigatory committee, I am going to ask all of you to stand up and swear or affirm an oath.

[Witnesses sworn.]

Mr. TOWNS. Just before the opening statements, I would like to yield to my colleague Congressman Schiff for a comment.

Mr. SCHIFF. Mr. Chairman, thank you for yielding. I'd like to go out of order for just a moment with this panel of witnesses. And you'll be given an opportunity in a moment to summarize your opening statements, but I believe you've all been here for the entire testimony. And I'm going out of order because I think there is one focal point I'd like to take up first with this panel, with your cooperation.

What Dr. Broder said in essence, at least, generally speaking, I think one cannot disagree with it. He's saying that recommendations from an institute like the National Cancer Institute, must have a sufficient basis in medical fact to be warranted and not just be an arbitrary statement of, "Well, we're from the Government, we told you to do it this way." And I think generally, I think we would all agree with that.

Acknowledging that there is a difference of opinion in this issue and in most issues, the question I would like to ask first, of the panel, is simply this question, to each of the witnesses in whatever order you wish to go in, in your opinion, is there a sufficient medical fact or consensus, whatever basis that you would make it, to say that the guideline of 1987 recommending mammography for women between the ages of 40 to 49 should be sustained today? Or whether there is not sufficient evidence and consensus and therefore the NCI did the correct thing in removing that guideline as, in their view, unsupportable by sufficient fact.

That is the question I'd like to pose first with your permission, Mr. Chairman, would invite anyone who—Dr. Kopans, let me start with you.

Dr. KOPANS. To answer your question simply—absolutely—there is good evidence to support the continuation of the screening guidelines. I would make one correction and that is that the consensus was arrived at in 1989, we keep hearing 1987 and 1988 from the National Cancer Institute. I have a press release from June 27, 1989, saying that's when the agreement was made. So to suggest that the agreement was 6 years old or whatever when the National

Cancer Institute revisited the issue, it was only about 3 to 4 years old. The consensus was only 3 to 4 years old.

I would point out, I think a question was asked by you, what new data were available since 1989 to cause a change in the guidelines. And the answer was the Canadian trial and then the trials from Sweden and Edinburgh. The Swedish trials actually were an aggregate showing a benefit for all women including those under age 50. And if we talk about individual trials, the benefits were even more striking in the Swedish trials. The Edinburgh trial also showed a benefit.

So the preponderance of the new data were positive evidence of benefit. The only contrary evidence was the Canadian trial, and in the Fletcher report, itself, if we ignore all the problems with the Canadian trial, and I could talk for an hour on all those problems, the Fletcher report itself says that those data will not even be available until 10 years after the trial. They looked at them much too early. So the aggregate of data support screening for women beginning by age 40.

Mr. SCHIFF. Dr. Smart.

Dr. SMART. Having been the one that was working at the NCI at the time these guidelines were instituted, September 30, 1987, was when the National Cancer Advisory Board, having already received the unanimous approval of the Board of Scientific Counselors, the National Cancer Advisory Board unanimously passed the guidelines. They were seven guidelines. Mammography was one of seven.

And so even though it didn't get published as a statement of 11 or 12 organizations until 1989, it actually happened at the NCI in 1987. I would like to say that the guidelines at the time of 1987 were based upon the existing trials as they existed at that point which showed good evidence in women over 50. There was still questionable evidence in women 40 to 49.

But the BCDDP had just been published as far as its 10 year report. And the BCDDP and 280,000 women showed equal benefit for women 40 to 49 as it did 50 to 59 and 60 to 69. So right at that moment, right at that moment we had the support of the BCDDP.

Mr. SCHIFF. Maybe you ought to say what the BCDDP——

Dr. SMART. The Breast Cancer Detection Demonstration project that was supported by the National Cancer Institute and the American Cancer Society. At that particular moment, that publication came out. And so it wasn't just randomized trials, but it was indirect evidence that we had from this big demonstration project.

Mr. SCHIFF. How about today? Today do you believe there is sufficient medical fact and consensus to warrant a continuation of the recommendation of mammography between the ages of 40 and 49?

Dr. SMART. It's a matter of the beholder. It's all in the eye of the beholder.

Mr. SCHIFF. How are you beholding it?

Dr. SMART. The way I'm beholding it is I think there is strong evidence, stronger evidence now than there was in 1987 for continuing the guideline, but I would say one thing, that is when you set up advisory committees and you hand choose the people that you're going to put on them and you limit so that they can only be randomized trials, and when those randomized trials only focus

on the first 7 years, when most of the evidence in women 40 to 49, starts at 8 and 9 years and goes on thereafter, you've already focused the trials, the consensus, so you're going to tell what the outcome is before you start.

Mr. SCHIFF. Making it more remarkable that the advisory group didn't do what the NCI wanted to do, I think.

Dr. Gerard, you've heard the question, what is your judgment on that question?

Dr. GERARD. I too question the word, "Sufficient." I think what is sufficient if you're a scientist is having very pure statistically significant data. I'm a clinician. I'm out there in the real world, dealing with real people, the women that Dr. Broder talked about.

And for me, looking at the data and understanding and reviewing all of the studies, one can clearly see there weren't enough women in these groups to show the statistical significance. You can look at each—almost all of the studies and see the very significant trends. You can look back at Sickles work using prognostic factors, like tumor size and lymph node involvement to give you a feel for what today's modern mammography will do. And you can say, "Yes, we're going to be saving lives by screening the women 40 to 49."

I have a responsibility to those women, and in my practice we're going to screen women 40 to 49. My job is going to be infinitely harder now. The job of my referring physicians, the internists, the OB/GYNs, the primary care doctors is going to be infinitely more difficult. They're now going to have to spend 15 minutes with each woman, going through the analysis of the studies.

Mr. SCHIFF. Dr. Alley.

Dr. ALLEY. I would agree. I think there really is good consensus among clinicians, the doctors that take care of patients, about the importance of screening mammography. So when they talk about consensus, I think the consensus is not lacking among practicing physicians for sure.

Mr. SCHIFF. All right. Dr. Cantwell.

Dr. CANTWELL. My greatest concern is about the African American woman in this country. We must realize there's been incredible paucity of data and a great underrepresentation of African American women in the clinical trials. In particular please note that, the Canadian study listed a total of 130 women who were classified as "Black." The study that has not been paid close attention to as Dr. Smart mentioned, is the BCDDP, the Breast Cancer Detection Demonstration project. Of the cancers in that study where there were a number of African American women participating, a total of 268 cancers were found in African American women, 48 percent of those cancers were in women who were below the age of 50 as compared to only 31 percent of the population overall.

Mr. SCHIFF. So if I understand, you believe there is sufficient reason to continue the guidelines as they were recommending the mammography for ages 40 to 49?

Dr. CANTWELL. I would strongly support screening.

Mr. SCHIFF. Well, Mr. Chairman, I realize there are different opinions and I mean no disrespect to those medical professionals who hold other opinions, but I just heard a five to zero, I think. I thank the panel, and Mr. Chairman, I thank you for letting me go out of turn to ask that question.

Mr. TOWNS. Thank you. At this time we will move forward. Dr. Alley, why don't you start.

STATEMENT OF KATHERINE ALLEY, M.D., ATTENDING SURGEON, GEORGE WASHINGTON UNIVERSITY HOSPITAL ON BEHALF OF AMERICAN CANCER SOCIETY

Dr. ALLEY. Good afternoon, Mr. Chairman and members of the subcommittee. I'm Katherine Alley representing the American Cancer Society. I'm grateful for the privilege to be here this afternoon. The American Cancer Society pledges its support to work with President Clinton and Members of Congress to enact health care reforms which meet the cancer prevention and control needs of all Americans.

My written statement provides details of specific recommendations relating to women's health. We support the principles of President Clinton's health reform plan. However, the Clinton plan is at variance with the breast cancer screening guidelines of the American Cancer Society and many other medical, health, and consumer groups.

The public debate over the value of screening mammography has caused concern and confusion among some women and health professionals. And worse, it has the potential for deterring women of all ages from getting a mammogram.

Those who oppose routine mammography for women aged 40 to 49, claim, in the words of the NCI statement, that randomized clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50. This statement is incomplete and, therefore, inaccurate. It would be more accurate to say that the current studies are inadequate to answer the question, "Does mammography save lives in women under the age of 50?"

The reason these studies are inadequate is that they were designed to look at the benefits of mammography over a wider age range of women. And because of this it's impossible to apply the results to a more limited age range as the 40 to 50 year old group. In the language of statistics, they are underpowered.

However, the majority of these studies suggest a benefit. It means that widespread participation in mammography screening among women in this age group could ultimately result in 2,000 to 3,000 fewer breast cancer deaths each year and perhaps, even more, as well as offering women options in treatment and improved quality of life.

Those who oppose screening will say that meta-analysis solves the problem of the inadequacy of individual study. However, these studies are almost impossible to combine due to variations in design technology, screening interval, and a whole host of other factors.

It is the assertion of the American Cancer Society that it is not good science to claim that mammography is not effective in this age group, when the research studies to date have been inadequate to answer the question. It is also not good science to say that the needs of women in this age group will be met if provisions are made to screen those who fall into certain risk categories. Allow me to point out how dangerous this approach would be since 80 percent of women with breast cancer have no risk factors. We know

this will leave the majority of women diagnosed in this age group unprotected. It is also not good public health.

Breast cancer represents a significant health problem to women of all ages and particularly those 40 to 49 years old. It's their No. 1 health concern, and with good reason; it's their No. 1 cause of death. The American Cancer Society cannot set women's needs aside because of a failure to study this question in such a manner that the existing evidence was as definitive as we have for women age 50 and older.

We believe that coverage should be available and that all women should talk with their providers to be fully apprised of the evidence. And in that context can reach an informed decision. We do support creative methods to pay for mammography, including term payments for women who are financially able to contribute to their own health care.

Finally, we believe that the administration should aggressively support studies of the question of efficacy of early detection in this age group. The existing trial data are inadequate to provide a definitive answer. And there has been a dramatic change in this technology during the 30 year period since the initiation of the first study of breast cancer screening. We believe these improvements have had a measurable impact on the ability of mammography to reduce mortality from breast cancer. The American Cancer Society has carefully evaluated the clinical trial data, data from other studies, and has carefully monitored the improvements in mammography during this period.

And we believe that data are sufficiently compelling to recommend mammography to women in this age group. Mammography is their single best opportunity to detect breast cancer early. We believe it makes a difference for them, just as it makes a difference for women over the age of 50. We also see the need for an ongoing program of research to better understand how to improve early detection. Indeed we need to have a better understanding of how to improve early breast cancer detection for all age groups of women. However, if statistically significant results from a randomized controlled trial are to be the only criteria by which reimbursement from mammography can be supported, then we believe that the administration must support the initiation of these studies at the earliest possible date.

Until we have definitive answers, however, women's access to mammography should not be limited. The economics of health care are important to the health care reform debate. And policymakers are struggling with the desire to match the availability of health care with those populations who need it most. We believe all lives that can be saved with this life saving tool of mammography should be saved.

In closing, Mr. Chairman, let me give some of this real meaning. I am one breast surgeon in one city in this country, and I have had 45 patients in the past 2 years who were under the age of 50 who are cured of their breast cancer because it was found at a preinvasive stage by routine mammography. I urge you to support the use of routine mammography in this group at a time when early detection is a patient's best hope for being cured. Thank you.

[The prepared statement of Dr. Alley follows:]

TESTIMONY OF

KATHERINE ALLEY, MD

ON BEHALF OF THE
AMERICAN CANCER SOCIETY

BEFORE THE HOUSE GOVERNMENT OPERATIONS COMMITTEE
SUBCOMMITTEE ON HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS

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Mr. Chairman and members of the Committee, I am grateful for the privilege to be here this morning. The American Cancer Society commends you for your concern of the impact of medical guidelines on health practice and our ability to reduce suffering and death from cancer.

The American Cancer Society is the nationwide, community-based voluntary health organization dedicated to eliminating cancer by preventing cancer, saving lives from cancer, and reducing suffering from cancer through research, education and service. The Society applauds the President and First Lady for making health reform a top priority and for bringing this issue to the American people. We recognize the leadership over the years of Members of this Committee and other Members of Congress, and renew our commitment to work with you to enact comprehensive health reform that will best meet the needs of cancer patients and those who are at risk of cancer, and to address the health care crisis in this country.

I do not use that phrase lightly. The quality of our nation's research program and available health care services, including state of the art technology and therapies to prevent and control disease, is arguably the best in the world. The majority of Americans who have health insurance coverage are pleased with the quality of care they receive. While these statements may be true, they are at odds with the fact that millions of uninsured, underinsured, and chronically ill Americans and their families do not receive even the most basic health care services. It ignores the fact that millions of Americans receive their care in hospital emergency rooms, at great cost to all in society, and more importantly at a time when their health problems may have progressed beyond the point of effective medical intervention. This system in crisis ignores the millions of Americans who are added to the ranks of the uninsured every year as rising costs of health care force businesses to abandon coverage for employees and their dependents. A band-aid approach to health reform will not address the never-ending cycle of rising costs and declining access, or the cost-shifting that occurs among governments, employers and employees, insurance companies, and tax payers.

Moreover, the current health care system dismisses the tens of millions of Americans suffering with disease, disability or other health disorders - including more than 8 million Americans living with cancer, and 1 million Americans who will be diagnosed with cancer this year alone. These individuals and their families are victims, not of cancer, but of a system that leaves them vulnerable at a time when they are fighting for their lives. Our current system locks cancer patients or their spouses or parents into jobs or other life situations for fear of losing whatever health care coverage they may receive for themselves and their family members. Too often cancer patients are forced into poverty in order to pay for continuing medical treatment and rehabilitation, as well as routine care because they lose their insurance coverage or it becomes unaffordable once they have a diagnosis of cancer or other health problem.

The American Cancer Society has adopted a Statement of Principles for Health Care System Reform which outlines these and other critical cancer prevention and control needs for all Americans. Today, we will speak specifically to the aspects of health reform that deal with women's health. Lung cancer is the number one cancer killer in women - 59,000 will die in 1994 alone - and tragically, smoking-related deaths are entirely preventable. We applaud one

of the most significant preventive health components of the President's health plan - a $.75 increase in the federal cigarette tax, and comparable increases for other tobacco products. The American Cancer Society, the American Heart Association, and the American Lung Association - united as the Coalition on Smoking OR Health - have called for a minimum tax increase of $2.00 per pack of cigarettes, a proposal that is supported by 66% of the American public. A major tobacco tax increase would simultaneously help pay for health care reform, offset the enormous burden tobacco imposes on our economy and, most importantly, discourage millions of young people from beginning to smoke in the first place, including record numbers of young women who are lured into the habit every day. Importantly, an increase of $2.00 per pack will save an estimated 1 million more lives over time than the President's proposed tax of $.75, and will bring in billions of dollars in additional revenues to support health care access.

One of the most important issues for those living with cancer is the adoption of provisions that will guarantee universal coverage for all women and men to timely, high-quality health care, including preventive health and cancer care. The American Cancer Society believes in individual responsibility. Everyone should contribute to the costs of their health care, and should be empowered with information about healthy lifestyle choices and ensured access to routine screening exams to save lives and reduce suffering. However, universal access can be compromised by the high cost of care and/or insurance premiums, and health reform should spread costs among all sectors so that everyone pays some share of health care and so that coverage for individuals is affordable and provides true "universal access".

In terms of benefits, the American Cancer Society has identified a wide range of services that should be provided for women who have cancer or who are at risk for cancer, including routine physical examinations which include appropriate preventive health counseling such as nutrition counseling and health education which examines the dangers of tobacco use, promotes breast and cervical cancer screening at intervals recommended by the American Cancer Society, and appropriate self-examinations for skin, breast and other cancers.

Upon diagnosis with cancer and other illness, all women should be provided with information about, and timely access to, high quality, state of the art diagnostic, treatment, and rehabilitative services. The American Cancer Society believes that any health reform plan should emphasize choice - that of the patient and the health care team, and ensure that the primary care physician act as facilitator, rather than gatekeeper, to obtaining care. We are also concerned that the definition of a primary health care provider be interpreted broadly to reflect the needs of cancer patients and others with specific health conditions. The American Cancer Society has called for increased participation by women in clinical studies and research trials of new drugs or therapies, preventive and screening/diagnostic care. Coverage should be provided for all women who participate in approved clinical trials, with full coverage for care given in conjunction with that trial. Clinical trials should be expanded for minority and underserved women. In addition, we support coverage for off-label (unlabeled indication) of approved cancer therapies or other modalities for all Americans, according to the standard available for Medicare beneficiaries.

Finally, it is critical that we significantly step up medical research to determine the cause and cure for all cancers, with special emphasis on priority cancers such as breast and ovarian, where we have little information about prevention or cure. Equally important is ensuring that our health care system facilitates the translation of research into clinical practice. We strongly recommend that Congress maintain and expand the public health service infrastructure that is a critical component, in conjunction with federal community health centers, state and local health departments, and community organizations like the American Cancer Society, in targeting and reaching underserved populations.

Mr. Chairman, in your invitation to the American Cancer Society, you asked us to discuss the issue of mammography screening guidelines, and to provide our guidance on how this will impact coverage under health reform. While we strongly support, in principle, the Clinton plan as it addresses many of the cancer control principles identified above, the President's plan is at variance with the breast cancer screening guidelines of the American Cancer Society and 21 other national medical organizations, health and consumer groups. The plan provides a routine screening mammogram for women aged 50 and over every two years, with no cost-sharing. The American Cancer Society recommends annual mammography for women ages 50 and over. The plan, however, does not provide for routine mammography for asymptomatic women between the ages of 40 and 49 years as is recommended by the American Cancer Society. A recent document provided by the Department of Health and Human Services clarifies the coverage under the Clinton plan, to say that women of any age who are defined to be at risk of breast cancer, may receive mammograms at a schedule "appropriate to their risk status", with no cost-sharing. The document further specifies that women of any age can receive mammograms at any time when they are "medically necessary or appropriate" as specified by the woman's health plan, with appropriate cost-sharing by the woman. The White House has explained that these benefits, and their exclusions, are based on the best and most recent scientific evidence. Let me express our concerns about this element of the plan, and it's alleged scientific basis.

First, the science. We have solid epidemiologic and clinical evidence that routine screening for breast cancer with mammography and clinical breast examination is effective in reducing breast cancer mortality. This conclusion is based on the evaluation of studies in which deaths from breast cancer were significantly lower in the groups invited to be screened with mammography compared with control groups that did not receive an invitation to screening. In effect, we have a proven intervention that can save women's lives at a time when we are unable to prevent this disease.

However, because each of these studies was carefully designed to test the efficacy of mammography in mortality reduction from breast cancer in a 25-30 year age-range of women, there are limitations to what they can tell us about the efficacy in 5-10 year age ranges of women, such as those between the ages of 40 and 49. In the language of statistics, they are underpowered, which means that there are too few women in the study for us to rule out that the findings, which in the majority of these studies suggest a benefit, did not occur by chance alone. Even the study recently conducted in Canada, which was specifically designed to address

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the 40-49 issue, has been judged to be statistically underpowered in addition to numerous other shortcomings that have compromised its potential to offer guidance on this question. This situation is analogous to the summary of a political poll, when listeners are told that the estimate of voter's preferences are accurate within 3 percentage points. The accuracy of the estimates of the benefit of mammography in women aged 40-49 in these studies is often in the range of 20-30 percentage points, meaning that it is entirely possible that the benefits are far greater than is suggested in the majority of existing studies. Potentially, between two and three thousand women's lives, or even more, could be saved each year through the availability of mammography for this age group. Indeed, we believe that the widespread participation among women in this age group during the past decade has already contributed to lives saved that otherwise would be lost, and that future breast cancer mortality statistics will bear this out. Importantly, detection of breast cancer at an early stage through mammography screening plays a large role in assuring better quality of life through improved treatment choices, in addition to potential for long-term survival.

In these public debates over the past year on the value of screening younger women, you have heard those who oppose this practice claim that there is no evidence of a benefit, or in the language of the recent statement from the National Cancer Institute that replaces their previous screening guidelines, "To date, randomized clinical trials have not shown a statistically significant reduction in mortality for women under the age of 50." The attempt at brevity leaves us with a half truth. It would be more accurate to say "It is not possible to have the same degree of scientific confidence about the benefit of mammography for women aged 40-49 as exists for women aged 50-69 due to inherent limitations in the studies that have been conducted to date."

Those who oppose the benefit will then respond that meta-analysis solves the problem of the inadequacy of individual studies. This may be useful in some instances, but theses studies are not easily combined due to variations in design, technology, screening interval, the inclusion or exclusion of clinical breast examination and quality. Cost-effectiveness issues are then raised, such as the comparatively lower incidence rate of breast cancer in women under age 50 compared to women aged 50 and older, and the higher ratio of benign to malignant biopsies in women under age 50 who are screened for breast cancer. However, more reasonable comparisons during this debate are for women aged 40-49 and aged 50-59. These differences are not nearly as great.

With respect to this appeal to the sober dispassion of the best and most recent science, it is our assertion that it is not good science to claim with confidence that mammography is not effective in this age group when the research studies to date have been inadequate to answer the questions. It is not good science to say that the needs of women in this age group will be met if provisions are made to screen those who fall into certain risk categories - we know this will leave the majority of women who will be diagnosed with breast cancer during this period of their lives unprotected. It is also not good public health. Breast cancer represents a significant health problem to women in this age group - it is their number one health concern, and with good reason. Among women aged 40-49, the incidence rate is nearly 10 times that of invasive

cervical cancer, and it is the leading cause of death from a single diagnosis. The American Cancer Society is unwilling to dismiss the potential benefit from this examination on the basis of inadequate experimental science, especially when we believe the inferential evidence from these studies and others point to a benefit for many women.

The American Cancer Society can not set these women's needs aside because of our failure to study this question in such a manner that the existing evidence was as definitive, one way or the other, as we have for women aged 50 and older. We believe that women should have access to breast cancer screening at intervals recommended by the American Cancer Society and the majority of medical and consumer groups that have taken a stand on this issue. We believe that women should talk with their providers, should be fully appraised of the evidence, and in that context can reach an informed decision. It is our position that if women chose to be screened with mammography, their provider should not play a gatekeeping role, but rather the role of the facilitator. It is critical that women are assured of timely and thorough follow-up in the event of an abnormal examination and the link to their provider should be primarily for that purpose. The American Cancer Society supports creative methods to pay for these examinations, including co-payments for women who are financially able to contribute to their own health care. We must not, however, deny early breast cancer detection to any woman who does not have the means to pay for the exam.

Finally, we believe that the administration should aggressively support studies of the question of the efficacy of early detection in this age group. The existing trial data are inadequate to provide a definitive answer, and there has been dramatic change in this technology during the 30 year period since the initiation of the first study of breast cancer screening. We believe these improvements have had a measurable impact on the ability of mammography to reduce mortality from breast cancer, and with appropriate practice guidelines and training for health professionals, have and can further help reduce the number of avoidable biopsies that are performed. The American Cancer Society has carefully evaluated the clinical trial data, data from other studies, and has carefully monitored the improvements in mammography during this period, and we believe that data are sufficiently compelling to recommend mammography to women in this age group. Mammography is their single best opportunity to detect breast cancer early. We believe it makes a difference for them just as it makes a difference for women over the age of 50. We also see the need for an ongoing program of research to better understand how to improve early detection in the delivery of this technology. Indeed, we need to have a better understanding of how to improve early breast cancer detection for all age groups of women. However, if statistically significant results from a randomized control trial are to be the only criteria by which reimbursement for mammography can be supported, then we believe that the Administration must support the initiation of these studies at the earliest possible date.

A majority of women aged 40 and older have never had a mammogram, and recent data show a steady growth in the proportion of women who report having a recent mammogram. We have implemented special initiatives targeting older women who are at most risk of breast cancer. Great progress has been made in bringing this technology to poor and underserved women, in large part through the efforts of the Centers for Disease Control (CDC) and its breast

and cervical cancer screening program that exists now in 45 states. Finally, great progress has been made in the technology and quality of mammography with passage of the Mammography Quality Standards Act of 1992, which will further impact the potential life-saving benefit of this procedure.

The American Cancer Society urges you to build on this progress. Over the years, we have made great strides in educating women about mammography, breaking down financial, physical and psychological barriers to women seeking mammography to our once universal guidelines. We fear that an unintended and unfortunate side effect of the current debate has been to cause widespread confusion and concern among women and physicians. There is very real concern that existing barriers and negative attitudes towards mammography will be reinforced by this conflicting and negative attention, and that this might drive women of all ages away from a confidence in mammography as today's most important means of fighting this deadly disease.

The economics of health care have become another important and undeniable aspect of all issues such as the one we are discussing today. Policy makers are struggling with the desire to match the availability of health care with those populations who need it most. We believe that ALL lives that CAN be saved with this lifesaving tool of mammography SHOULD be saved.

In addition to the progress that has been made with existing technology, there are exciting new developments emerging in genetic markers and different modalities of imaging. We need to pursue the existing questions and new questions aggressively, and the American Cancer Society believes that women should not be denied access to this technology during these investigations. We strongly endorse that routine mammography be made available to women between the ages of 40-49 and that the Administration support an aggressive research program related to improving the application of existing technology and emerging technology to identify women with breast cancer and those at risk of breast cancer. We also strongly endorse that this program not be at the expense of research targeted to prevention and cure of breast cancer, or other critical research programs.

In conclusion, the American Cancer Society strongly disagrees with any change in reimbursement for mammography screening at this time, based on exiting studies, and calls on Congress to make mammography available to all women at the frequency intervals recommended by the American Cancer Society. Mammography offers strong potential to save lives from cancer and if detected early, provides a woman with increased options for treatment and improved quality of life. Under health reform, the American Cancer Society believes that routine mammography should be available on a routine basis to women over the age of 50 on an annual basis with no cost-sharing, and for women age 40-49, every 1-2 years based on risk and other factors discussed between the woman and her physician. Breast cancer is a major problem for all women, including women aged 40-49, and they should not be left without access to this procedure. Finally, the flexibility indicated by the Administration for screening women of all ages, must not be left to the determination of individual health or corporate alliances, but should be standardized in guaranteed minimum benefits. Clinical breast examination and instruction in breast self-examination are integral components of breast health care and should

be available to all women at age intervals recommended by the American Cancer Society.

Thank you.

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Mr. TOWNS. Thank you, Dr. Alley. Dr. Smart, let me thank you in particular today. I understand that you came all the way in from Geneva, Switzerland.

Dr. SMART. That's right.

Mr. TOWNS. We certainly appreciate that.

Dr. SMART. I feel strongly about the subject.

Mr. TOWNS. Thank you. Thank you.

STATEMENT OF CHARLES R. SMART, M.D., RETIRED CHIEF OF EARLY DETECTION BRANCH, NATIONAL CANCER INSTITUTE

Dr. SMART. I was the Director of the Cancer Department, Early Detection Department or Division at the time that these guidelines went into effect in 1987. You have asked me about six questions and I will try to answer them briefly.

The first question was the validity of NCI's use of clinical trials as a basis to eliminate the guidelines. They reviewed these eight trials at their meeting in February 1993. And at that particular time there was a meta-analysis done but it was limited to the first 7 years. And the meta-analysis of the first 7 years did not show a statistically significant benefit for women 40 to 49.

Dr. Chu [from the Early Detection Branch at NCI] took the data from that particular group and gathered additional followup and he did a meta-analysis which is the one that Dr. Broder—asked for from the Early Detection Branch. And that was done by Dr. Chu and Dr. Tarone Cherone and it showed a statistically significant benefit at the 0.041 level, showing a 17 percent reduction in mortality when you consider all the trials, excluding the Canadian trial.

Now the NCI, the people in the Early Detection Branch that took my place, they feel that you cannot exclude the Canadian trial. I happen to believe that you can exclude the Canadian trial having looked at it very closely. I believe—they did not pass that article by Dr. Chu up, it never got to Dr. Greenwald until later, it never got to Dr. Broder, it never got to anybody considering the problem at the National Cancer Institute. Everything that Dr. Broder said was exactly correct, based upon the different committees that met, but there was this bit of information which was never forwarded from the branch level.

I would like to say this, that if there is research based on indirect evidence demonstrating the benefit of mammography screening for women between the ages of 40 and 49. The BCDDP screened 280,000 women, of which we had 1,000 women, 1,004 women with breast cancer in their 40 to 49 age group, we had 1,560 that were 50 to 59, we had 1,000 that were 60 to 69. In the BCDDP, the modes of detection, the early detection, the percentage that were detected by mammography, were the same. The distribution of cases were the same. The survival was the same. The death rates were the same. If there is a benefit in women 50 to 59 and 60 to 69, there is certainly a benefit for women 40 to 49 based upon this series, the largest that has ever been done.

However, the BCDDP was not a randomized trial, and therefore was not considered, in fact, it was not allowed to be discussed at the international meeting last February 1993.

I would like to say that mammography, from the time of the HIP study, showed that in women who were 40 to 49, only 40 percent of them could be detected by mammography. In the BCDDP, 10 years later, 90 percent could be detected by mammography. In the women who were older than 50 years of age, 50 to 59, in the HIP study in the sixties, only 60 percent could be detected by mammography. In the BCDDP, 93 percent could be detected by mammography. So in the day of the BCDDP with two view, on an annual basis, plus physical examination but just considering mammography alone, there was a tremendous improvement and equal, you might say, detection rates between the two.

The one thing that we heard a few minutes ago the Congressman from Florida quoting the fact that I said that I only picked up two cancers per thousand no matter what the age group. The BCDDP was most interesting in the fact that after the first screen—in the first screen there was a big difference between women 40 to 49, 50 to 59, 60 to 69, and 70 to 79. It was like that. I mean, it increased greatly.

On the second screen it stayed the same, two, two, two, two, and two, cost effectively, it was just as effective to screen a woman 45 to 49 as it was a woman 60 to 69. And the only thing I was trying to make a point of was that cost effectively and yield wise and effort wise, it was the same.

OK. I would like to just make one last statement. And that is, the impact that the change in guidelines will have on women. In my opinion, breast cancer screening has not only been set back for women 40 to 49 years of age, but for women of all ages. There is evidence that the women 40 to 49 years of age are bellringers, they lead out. They are movers and shakers. The change has added further to the confusion of the world, confusion in the world of breast cancer screening. What did they say about international? There is a question about the international science community. Five out of the eight studies are from Sweden. They showed a 13 percent reduction in mortality rate even though they had no physical examination, they had one view, and it was only done every 2 years. They have now changed, and there's a national policy in Sweden based on their own studies. It says that, "We will screen women 40 to 49 every 12 to 18 months. And we will use two-view mammography."

Thank you.

[The prepared statement of Dr. Smart follows:]

TESTIMONY OF CHARLES R. SMART, M.D.
Retired Chief of Early Detection Branch, DCPC, NCI
March 8, 1994

Testimony given before the Human Resources and Intergovernmental Relations Subcommittee of the House Government Operations Committee on **NCI's decision to revise its mammography guidelines. Question 1 The validity of NCI's use of randomized clinical trials (RCT) as a basis to eliminate the guidelines?** The answer depends upon the orientation of those asking the question. What is scientifically possible and if possible how scientific do they insist on being? Nearly all of the NCI's guidelines - skin, oral, colorectal, testicular, prostate were not based on clinical trial evidence of decreasing mortality but on the best evidence available, mostly indirect as is nearly the total field of epidemiology and most of medicine. If the screening RCT is the basis of all recommendations for cancer screening then the most common procedures with the most successful treatments, such as inspection of the skin for cancer, cannot be recommended. In dropping the recommendation for mammography in women 40-49 years of age, the Fletcher committee considered only screening RCT's first 7 years of follow-up while most of the studies show a benefit after 8 or 9 years with the statistical significance being debated. They are unwilling to consider anything but RCT's.

Treatment RCT's dealing with patients already diagnosed with cancer (1:1) are possible and practical, the trial size is manageable and the time span is relatively short.The size of the trial is dependent upon the estimated difference in expected outcome based upon the results of descriptive non-randomized studies. The end-points are most often measured in months such as in chemotherapy measuring the percentage reduction in cancer size and duration versus the morbidity. In surgery and radiation the measures are the percentage developing local recurrences or distant metastases and the disease free interval. **Prevention RCT's** require far greater numbers (1:500-1000) depending upon the population and the end point is developing cancer over a period of years. **Screening RCT's** require still greater numbers (depend upon the expected incidence of the cancer in the normal population) screened 1-8/1000 on the first screen 1-2/1000 on subsequent screens in the 3 or 4 most common cancers. In screening RCT's the end-point is deaths from the specific cancer over a period of many years. The accurate cause of death must be determined in the entire trial population over a period of 10 to 20 years. In screening RTC several other problems have to be considered which limits its usefulness: (1) For other than the 3 or 4 most common cancers, the rarity of the disease in the general population makes RCT's sample sizes nearly impossible. (2) The death end-point makes the length of such trials (10-20 years) impractical, the technology will likely be outmoded before the trial is completed. (2) Contamination of the control group with the procedure being studied. Anything in common medical practice is very difficult if not impossible prove efficacy in a randomized trial. (3) Compliance - many in the study group choose not to participate. This greatly weakens the study and underestimates its possible benefit or statistical significance.

Question 2 Your research on indirect evidence demonstrating the benefit of mammography screening for women between 40 and 49.

Randomized breast cancer screening trials are helpful in establishing evidence of benefit when they yield statistically significant results. The results of individual randomized screening trials can vary greatly depending upon the quality of the images, the frequency of screening, compliance, contamination sample size and the length and adequacy of followup. In women 40-49 years of age the first randomized breast cancer screening trial, the Health Insurance Program of Greater New York (HIP study) showed a statistically significant decrease of 24% in breast cancer mortality at 18 years followup, virtually the same as the 23% decrease seen in women 50-59 years of age. At 10 to 12 years of follow up five of seven randomized trials have shown a non-statistical decreases in breast cancer mortality. No trials with less than eight years followup have shown a decrease in mortality for women 40-49 years of age; whereas seven trials have shown a decrease in women over 50 years of age.

The largest study of screening women age 40-49 (93,471) comes from the Breast Cancer Detection Demonstration Program (BCDDP). This demonstration program was not a randomized trial but yields indirect supportive evidence for screening women age 40-49, by comparing age group results . Three highlights are presented: (1) Mammography in the BCDDP (1970's) was greatly improved compared to the HIP (1960's) study. Mammography detected 40% of the cancers in women 40-49 years of age in the HIP compared to 90% in the BCDDP. In women 50-59 years of age mammography detected 60% in the HIP but 92% in the BCDDP. (2) Using annual two-view mammography plus clinical breast examination after the first screen of women 45 years of age and older subsequent detection rates were virtually the same for all age groups. The number of women screened annually yields slightly over 2 breast cancers per 1000 women regardless of age group. (3) Similar types, sizes, stage distributions and survival and case fatality rates were demonstrated in women 40-49, 50-59 and 60-69 years of age.

Questions 3 & 7 Your analysis of the internal dynamics at NCI behind the change in guidelines and the origin of the guidelines? In my opinion it was a change in orientation from a coalition opinion based on best evidence to hardline limited randomized trial evidence.

The guidelines where developed in 1986 and 1987 with the assistance and consultation of medical specialty organizations considering the best available evidence - direct as from randomized screening trials and indirect from the data in the population based Surveillance Epidemiology and End-Results (SEER) program and from randomized treatment trials and descriptive studies. Most of the medical professional organizations adopted

these guidelines or a close variation in their organizations. The DCPC board of Scientific Advisors unanimously passed the guidelines in mid-September 1987 as well as the National Cancer Advisory Board on September 30th, 1987 followed by the executive committee of NCI.

At this time a publication of the 18 year follow-up of the HIP study, with special attention to women 40-49 was published by Chu, Tyrone and Smart showing a statistically significant reduction of 24% in women screened when 40-49 as compared to a 23% reduction in women 50-59 years of age. This was using a different more sensitive statistical methodology than the usual poisson calculations which was a point of controversy based on orientation.

The guidelines when approved were called "Working Guidelines" meaning they were not set in stone, but with the presentation of new data would be reconsidered and possibly changed.

When the Canadian Study was made public in November 1992, stating that their was no statistical evidence of benefit in women screened in ages 40-49 at 5-7 years, the Early Detection Branch and the Biometry Branch jointly sponsored an international breast cancer screening workshop on February 24 & 25th, 1992 in Bethesda. All countries with randomized trials were invited to participate and present their data. I was asked to discuss the HIP study. The essence of the discussion was "WHAT YOU SEE IS WHAT YOU GET" (WYSIWYG) the long term follow-up shows a decrease in mortality among women who entered screening when they were 40-49 years of age. I said "this is further supported by the largest screening study ever done, the Breast Cancer Detection Demonstration Project (BCDDP) in which over half of the 280,000 women screened were under 50 years of age with 93,000 being 40-49 years of age. At 14 years of follow-up the survival and death rates were the same for women 40-49, 50-59 and 60-69 years of age with over 1000 women in each group. The percentages detected by mammography were virtually the same, as were the stage distributions at diagnosis. all supporting the findings of the HIP study of equal benefit. The discussion was ignored and never appeared in any of the summaries of the meetings. The objections to limiting presentation and discussion to only randomized trial data was made by many.

The conclusions of the Fletcher committee were reported to the Presidents Breast Cancer Panel and then to NCI. The DCPC Board of Scientific Advisors upheld the recommendation to drop the recommendation to screen women 40-49 saying the evidence of benefit from randomized trials was not clear. The National Cancer Advisory Board (14 to 1) opposed changing the guidelines which was as close as it ever got to having any representation or consultation with the twelve medical professional organizations that created the guideline. The executive committee chose to

follow the strict line of randomized clinical trial evidence basically limited to 7 years of follow-up.

Question 4 The impact the change in guidelines will have on women? In my opinion, breast cancer screening has not only been set back for women 40-49 years of age, but for women of all ages. There is evidence that women 40-49 years of age are the "Bell Ringers", those that lead out, the movers and the shakers. If women 40-49 were lost to mammographic breast cancer screening all women might suffer. As it is, I believe that the change in NCI's guidelines, without the concurrence of the medical professional organizations or the American Cancer Society, than while causing confusion in the world of breast cancer screening, their will be little set back in the pattern of breast cancer screening in the U.S.

Question 5 The support in the international science community for mammographic screening for women between 40-49 years of age?

There is little doubt that clearer information is needed and may be forth coming with further follow-up of the randomized trials.Unfortunately, many trials have utilized less than optimal mammography in younger women using a single view every two years without the benefit of a clinical breast examination. Those in the business of running randomized trials in other countries have been meeting regularly and comparing and publishing their results. At least half of them support the actions of the NCI in changing the guidelines. In Sweden however, they have now instituted two view mammography every 12 to 18 months in a national breast cancer screening program for women 40-49 years of age. The data from their 5 randomized trials have shown a 13% (not statistically significant) decrease in mortality beginning after the 9th year. A decrease is also being seen in the Edenbrough trial (not statistically significant).

Question 6 My views on alternative screening methods and the feasibility of establishing a randomized clinical trial to determine the benefits of mammography in women in their 40's?

In my opinion, presently there is no procedure to detect breast cancer nearly as well as mammography. Ultrasound and MRI continue to be investigated.

The feasibility of a 10 year international randomized trial of mammography in women in their early 40's is being contemplated. In the U.S., because of the large amount of screening already going on in women 40-49 years of age, the size and duration of such a trial seems prohibitive, 1.5 million women being screened and followed for 10 to 20 years. It may still be possible to do such a trial in Europe where their has been less screening of women in this age group. England has been planning such a trial

Addendum Testimony of Charles R. Smart, M.D.
Retired Chief of the Early Detection Branch, NCI

In my opinion, the reason for the change in the breast cancer screening guidelines at the NCI is principally a change in the philosophy of the leadership. Now all emphasis is being placed soley on randomized screening trials which are impractical for most cancer sites. In 1963 the first randomized cancer screening program was funded by NCI. In 1969, six years later when a 30% reduction in breast cancer mortality was reported, a new dogma emerged, that randomized cancer screening trials were the only source of valid evidence of benefit. Rather than accepting the principal that screening detected cancers earlier when smaller and more successfully treated, two new theoretical screening baises were introduced. Lead time bias where earlier diagnosis and treatment did not extend the length of life but (assuming ineffective treatment) only increased the length of the awareness of having cancer from diagnosis to death. The second was length bias where in screening asymptomatic populations, indolent cancers might be detected which ordinarily may not have caused harm during life and biased survival results. Concern over avoiding these two biases have influenced some scientists to accept only a reduction in deaths in a randomized screening trial as evidence of benefit. The original NCI guidelines were based upon the best evidence available, randomized or non-randomized. The previous recommendations for the mammographic screening of women age 40-49 were based upon the results of the non-randomized Breast Cancer Detection Demonstration Project (BCDDP) which the present leadership and consensus groups (medical practice organizations were excluded) have been unwilling to admit as evidence.

The following are some of the reasons randomized cancer screening trials have trouble reaching statistical significance and are only practical in 3 or 4 of the most common cancer sites:

(1) Trial size - in the present NCI trial for prostate, colorectal, lung and ovary (PCLO) 150,000 individuals will be registered in the trial 75,000 men and 75,000 women. For the study of lung and colorectal cancers there will be 150,000 and for both prostate and ovary 75,000 each. The rarer the cancer type the larger the trial that is required, so that for the less common sites such as melanoma of the skin etc the estimated trial size goes over 500,000. It has been estimated that at present in the U.S. it would take 1,500,000 woman age 40-41 to mount a randomized mammography trial with a duration of 10 to 20 years. The subgroup analysis of trials that were designed to show statistical significance for a broad range of ages i.e. 40-70, could not be expected to show statistical significance for the narrower spectrum of 40-49.

(2) Compliance - the percentage of women in the study group,

offered screening, who agree to be screened. In the original HIP study 10,000 out of the 30,000 in the study group refused screening. Compliance was 67%. The entire study group that were invited to be screened have to be considered as though they were screened when compared to the control group to determine the difference in numbers of deaths from breast cancer. A low compliance greatly reduces the ability to show a statistical difference or requires an increase in the size of the trial.

(3) **Contamination** or cross-over - ideally one would like to randomize to be screened (study group) or not screened (control group). Many women in the control group in the Canadian study received mammography (26% of those that had breast cancer), called contamination. This again lessens the differences between the study and control groups and limits the ability to reach statistical significance. At present in the U.S. a large percentage of women (70%) between the ages of 40-74 have had at least 1 mammogram which would make it difficult to have a randomized control group that did not have a high degree of contamination. In screening for other cancers such as skin cancer where the procedure is public education and physician examination - the procedure is in such common practice as to make a trial nearly impossible (does this mean there should be no guidelines because there could be no randomized trial?).

(4) **Follow-up** - the trial must have sufficient cancers detected and then the entire population needs to be followed until there have been enough deaths to have a statistically significant difference between the study and the control groups. The cause of death from any cause has to be determined for every death in the entire trial population over a 10 to 20 year period. The cost of follow-up is generally greater than the cost of screening the study group 4 or 5 times.

In 1985, when I came to NCI, the only recommendations for screening or early detection were for breast cancer over the age of 50 and for cancer of the cervix. After many meetings, both internal and external to the NCI, it was apparent that if one adhered only to the philosophy that nothing could be recommended in guidelines that did not show a statistically significant reduction in mortality in a randomized trial, then most of what doctors were doing in their offices to detect skin, oral, colorectal, prostate, testicular, ovarian, uterine and soft tissue cancers could never be recommended. It was suggested by our consultants that the best evidence from all sources be considered in concert with representatives of the medical professional societies. The outcome of many meetings with these groups was the development of seven guidelines, including mammographic screening of women 40-49 years of age, which were also endorsed by most of the organizations. In September 1987 these guidelines were unanimously supported by the Board of Scientific Counselors of the Division of Cancer Prevention and

Control as well as by the National Cancer Advisory Board and the NCI's executive committee. Some within the biometry branch did not approve of any of the guidelines except for screening women over 50 with mammography and physical examination and for cervical screening.

In 1989, the US Preventative Services Task Force of HHS, released their 5 year study, based upon randomized trials as published in the medical literature. They could only recommend screening for breast over 50 and cervical cancer screening where supported. However, a few high risk screening recommendations were made on the basis of clinical prudence. My opposition to their recommendations, in an invited presentation, at the time of their release at the 100 anniversary celebration of the Johns Hopkins School of Public Health was followed by a lost pay check (automatic bank deposits) for 4 consecutive pay periods; the only occurrence in six years. This was followed by a personal request from HHS to my leader, Dr. Peter Greenwald, to have me dismissed. My leaders response was that he was in agreement with my presentation. Thus, two arms of the government had opposing early cancer detection guidelines.

In 1990, when Dr. Broder became the director of NCI, he expressed the personal opinion that he did not believe there was evidence to support mammographic screening of women 40-49 years of age. I was having health problems and determined that it was time to leave the government which I did June 30th, 1991. I was given an award for my participation in the development of the NCI Guidelines for Early Cancer Detection. After departing, those that favored only guidelines supported by randomized trials had little opposition in re-establishing their influence by having an "International Workshops on Screening for Breast Cancer", February 24-25, 1993 and allowing only randomized trial data to be considered and allowing no minority reports. A meta-analysis included only the first 5-7 years data which showed no evidence of benefit. Their report stated "There is an uncertain and, if present, marginal reduction in mortality at about 10 to 12 years. Only one study provides information on long-term effects beyond 12 years, and more information is needed. More research results should be available relatively soon. Continued analysis from the combined Swedish experience is needed". The BCDDP was the basis of the NCI and ACS's guidelines for screening women 40-49, the largest study ever done; it was not allowed because it was not a randomized trial. The project had been funded 1973-1981, 1988 by NCI and ACS of 280,000 women age 35-74 and followed for 14 years. One half of the women were under 50 years of age. It showed equal benefit for women detected as having breast cancer whether in their 40's, 50's or 60's.

One member of the Early Detection Branch, updated the Swedish and Edinburgh studies and performed another meta-analysis. He excluded the Canadian trial because of insufficient length of

follow-up, mammographic quality and questions concerning randomization. His meta-analysis showed an 18% (p=0.042) statistically significant reduction in mortality for women 40-49 years of age. On October 20th when NCI was advertising for response to their proposed dropping of the recommendation for the mammographic screening women age 40-49. The new meta-analysis was delayed in its review and reached Dr. Greewald in late November. Dr. Greenwald's response was that the study was flawed by the omission of the Canadian data and a better study was planned for January 1994.

In December 1993, despite a 14 to 1 vote of the NCAB, the executive committee dropped the recommendation for mammographic screening of women 40-49 years of age, in my opinion because of sole reliance on the first 7 years of randomized trial data despite the known delayed reduction in mortality for younger women (8-12 years).

On February 23, 1994 the NCAB voted unanimously that NCI not involve itself independently in the setting of health care policy.

Mr. TOWNS. Thank you, Dr. Smart. Dr. Kopans.

STATEMENT OF DANIEL B. KOPANS, M.D., DIRECTOR OF BREAST IMAGING, MASSACHUSETTS GENERAL HOSPITAL

Dr. KOPANS. Mr. Chairman, members of the subcommittee, I want to thank you for giving me the opportunity to talk to you today. I am submitting written materials that I hope you will include in the official record.

Mr. TOWNS. The entire statement will be included in the record.

Dr. KOPANS. Thank you. There is no question that I come to you with a bias in that I see on a daily basis the ability that we now have to detect breast cancers by mammographic screening in women of all ages at a smaller size and earlier stage than ever before, and that this has made it possible for women to have many more options in their treatment when breast cancer is discovered.

As I have outlined in my written testimony, the mammography screening trials and other screening programs, as Dr. Smart just alluded to, provide strong evidence that periodic screening using mammography beginning by age 40 can reduce the rate of death from breast cancer.

The decision by the National Cancer Institute to change the guidelines was ill considered, scientifically unjustified, and their new recommendations are inconsistent and not based on scientific evidence. The new NCI analysis has led to a great deal of confusion and will likely result in the elimination of significant mammographic screening for women ages 40 to 49. Although women who can afford to be screened may continue to avail themselves of the benefits, disadvantaged women will likely be denied access to screening. Lives that could be saved will be lost.

Many women and their physicians have already interpreted the changed recommendations as proof that there is no screening benefit. The National Cancer Institute dramatically emphasizes, and we heard again today from Dr. Broder, the relationship between doctor and patient in a decision whether mammography is appropriate, and the NCI has championed full disclosure of the available information so that this can be an informed decision.

I completely agree with this but it is grossly hypocritical for the National Cancer Institute to take this moral high ground since it has never presented all sides of the issue to the public. The National Cancer Institute has actively promoted its point of view while ignoring alternative analyses of the data and, as a national institution, has monopolized the media in providing its one-sided interpretation.

This has been in the form of misleading information to the public. For example, we heard Dr. Broder say that 80 percent of breast cancers occur in women 50 and over. NCI often repeats this. As with most of their analyses, they are comparing women in one decade of life to the sum of all women from the older four decades, ages 50 to 90.

A more appropriate comparison would be to women ages 50 to 59, women who the National Cancer Institute strongly and correctly urges be screened. NCI is well aware that in 1993 in the United States there were almost the same number of cancers diagnosed among women ages 40 to 49 as among women ages 50 to 59.

With only an 8 percent difference, it is clear that the problem of breast cancer is as significant for women ages 40 to 49 as for women in their fifties.

In its effort to downplay the importance of breast cancer among younger women, the NCI has also neglected to point out that at least 40 percent of the years of life lost to breast cancer occur among women diagnosed under the age of 50.

Incongruously, NCI in its background information had stated that the mortality rate for women in the United States ages 40 to 49 has decreased over the past several years and they state in part, "due to early detection." Yet now when progress is appearing they propose that we quit.

NCI's one-sided assessment has led women and their physicians to interpret the changes in breast cancer screening guidelines as suggesting that the studies have been done, women ages 40 to 49 have been given the opportunity, and the data show no benefit. This is absolutely not true.

The available trials, as we've already heard, were not designed to evaluate women ages 40 to 49 as a separate group but, rather, women over larger ranges of age. Even all the trials put together have involved less than one half the number of women under 50 that would be needed to provide the statistical power to be able to satisfy the National Cancer Institute requirement.

From a scientific perspective the NCI's argument is specious. There is, in fact, clear evidence that screening can reduce the death rate for women under the age of 50. The NCI has failed to point out that if the mature trials are evaluated as they were designed without being weakened by statistically dangerous subgroup division, they demonstrate a statistically significant mortality reduction for women who begin screening by age 40.

At least five out of the eight clinical trials show a clear benefit for these younger women even when subgroup analysis is done that ranges from 23 percent in the health insurance plan trial to 49 percent in the Malmo trial. The National Cancer Institute is aware of these data and yet dismisses them, incredibly stating that they do not even represent a trend.

Proponents of mammography screening have no illusions that mammography is the solution to the breast cancer problem. Research into the causes, methods of prevention, or universal cures must be continued. Until these are found, mammography for women on an annual basis beginning by age 40 can reduce the rate of breast cancer deaths.

I would prefer that NCI follow the available scientific evidence and support screening younger women, but I recognize that this is not likely. Since the NCI has clearly stated that experts disagree, they owe it to American women to explain why there is disagreement and what the other experts suggest.

The National Cancer Institute should provide the full disclosure that it has suggested it wants for women and their physicians. As a minimum, I would suggest the following be added to the NCI recommendation:

Women and physicians should be aware that other experts interpret the available data as suggesting a benefit for the mammographic screening of women ages 40 to 49 that is similar to that for women ages 50 to 59. Experts have pointed out that

the data reviewed come from trials that lack the statistical power to provide statistically significant results; nevertheless, there is a trend toward benefit that has been seen in at least five out of the eight screening trials and strong evidence from other studies that women ages 40 to 49 can benefit from mammographic screening.

You asked Dr. Broder earlier to provide the information that he is saying women should use to make their decisions. I sent Dr. Broder at least 12 points of information that I suggested be forwarded to women to help them make a considered judgment. I have not seen that published in anything from the National Cancer Institute as yet.

Again, I would like to thank you, Mr. Chairman and the subcommittee, for giving me the time to discuss these issues.

[The prepared statement of Dr. Kopans follows:]

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Human Resources and Intergovernmental Relations
Subcommittee of the House Government Operations Committee
2157 Rayburn House Office Building
Washington, DC 20515

Hearing to Review the National Cancer Institute's Decision to Revise Its Mammography Guidelines

STATEMENT

Daniel B. Kopans, M.D.

Associate Professor of Radiology
Harvard Medical School
Director of Breast Imaging
Massachusetts General Hospital

My name is Dr. Daniel Kopans. I am an associate professor of radiology at the Harvard Medical School and Director of the Breast Imaging Division at the Massachusetts General Hospital. I am a Fellow of the American College of Radiology and a member of its Breast Task Force. I have written over 120 papers that have been published in peer reviewed journals on the subject of breast cancer detection and diagnosis. My textbook on the subject is among the most widely used in this country and I am an internationally recognized expert in this field. I was one of three radiologists who was asked by the investigators of the National Breast Screening Study of Canada (NBSS) to review the quality of the mammography in that trial, and I was invited by the National Cancer Institute (NCI) to speak as a panelist at the "International Workshop on Screening for Breast Cancer" last February. I was invited by the American Cancer Society to discuss breast cancer screening at their National Conference on Breast Cancer last August, and was an invited participant at the International Union Against Cancer (UICC) meeting that reviewed the data on screening younger women last October.

The recent decision by the National Cancer Institute (NCI) to withdraw support for mammographic screening for women ages 40-49 is unfortunate, ill-advised and scientifically not justified. Since time will not permit me to enumerate all of the problems with the Institute's analysis that resulted in the new guidelines, I have also provided a more detailed review for the Committee.

The fact that the Executive Committee of the National Cancer Institute ignored the recommendations of both its National Cancer Advisory Board (NCAB), as well as its

Board of Scientific Counselors (BSC) is extremely unusual, and can only be attributed to either arrogance, or political pressure. There was no reason to rush to change the guidelines over the objections of these advisory groups as well the concerns raised by many other groups and cancer experts. It can be no coincidence that the new NCI guidelines are now concordant with the administration's proposed new Health Plan.

There is ample evidence that screening mammography can reduce the size and stage at detection of breast cancers for women ages 40-49 and that this can result in reduced breast cancer deaths. Controversy has arisen because the NCI analysts have improperly used data from trials that were not designed or performed adequately to answer the questions being asked.

The NCI has sought "proof" that screening women ages 40-49 can reduce the rate of deaths from breast cancer. "Proof" of benefit is measured statistically. It is generally accepted that the benefits of screening can only be demonstrated through clinical trials that randomly divide large numbers of women into two demographically similar groups and then compare breast cancer deaths among the screened women to the control group that is not screened. There have been 8 such trials performed to date. One in the United States, 6 in Europe, and 1 in Canada. There have been many problems with evaluating the results of the data from these trials since they were not designed to evaluate the specific group of women ages 40-49. The trials differed in their design and performance. At least half the trials used single view mammography which has been shown to overlook as many as 10% of breast cancers. The available data suggest that women in this age group should be screened every year. Most of the trials screened women under 50 at longer intervals than 1 year. Other problems with the trials include the fact that many women who were offered screening refused to be screened, and many women who were counted as unscreened controls had mammograms outside the trials.

Disregarding all of the other problems with the trials, the basic weakness in the NCI analysis lies in the statistical significance of the data. This is a key element in the debate. Statistical significance is based on mathematical formulas that are used to try to determine whether results are likely to be real or possibly due to chance. As with political polls, the significance of the results from clinical trials is dependent on the number of women who participate. Large trials are needed to provide the statistical power to confirm that any benefit that appears is not due to chance. The design and performance of these trials is, therefore, critical to their success. In order for data to be valid, the results of a trial must be evaluated with an appropriate understanding of the parameters of the trial. If the benefits of screening are to be evaluated for a specific age group, this must be determined prior to the start of the trial to insure that there are sufficient numbers of women who participate at the ages in question, and that the screening parameters, such as the time between screens, the number of mammographic projections, etc., are appropriate for the "sub-group" to be analyzed. Basic guidelines for performing clinical trials warn analysts that unplanned analysis of sub-groups can be grossly misleading, yet this is exactly what the NCI has done.

The NCI has continually ignored the fact that, with the exception of the National Breast Screening Study of Canada (NBSS), none of the 7 other trials were designed to evaluate the sub-group of women ages 40-49 separately. None of the trials, including the NBSS, has sufficient numbers of women ages 40-49 to be able to "prove" an expected mortality reduction of 25-30% with statistical significance. When asked which of the trials has sufficient statistical power, NCI has repeatedly avoided the question and replied that they "believe" that a meta-analysis, performed using outdated information, was sufficient. [Meta-analysis is a method that tries to combine the results of different trials together to increase the overall statistical power]. Reliance on "belief" is inappropriate for the leading

national scientific organization. Because of the widely varying trial protocols, it is unclear whether a meta-analysis is even valid. Furthermore, there are mathematical formulas that determine the statistical power of the trials. The NCI is well aware that none of the trials individually or collectively has sufficient power to provide the "absolute proof" that they require. The NCI is presently exploring the possibility of performing a new trial to evaluate the benefit of screening women in this decade of life. If the data were sufficient to alter the guidelines, there would be no need for a new trial.

Unfortunately, the NCI's one sided assessment has led women and their physicians to interpret the changes in breast cancer screening guidelines as suggesting that the studies have been done, women ages 40-49 have been given the opportunity, and the data show no benefit. This is absolutely not true. From a scientific perspective, the NCI's argument is specious since *none* of the randomized, controlled trials have been designed with the statistical power to be able to provide this type of "proof". In order to have the required statistical power, it has been estimated that a trial would necessitate the participation of almost 500,000 women ages 40-49. Because they were not designed for sub-group analysis, all the 8 trials put together have involved fewer than 170,000 women under the age of 50. At the October meeting of the International Union Against Breast Cancer (UICC), members of the NCI joined representatives of the international scientific community in unanimous agreement that the trials had insufficient power. The NCI should explain why in private it affirms the absence of statistical power in the trials, yet has not conveyed this to the public. Some now counter that if such a large trial is needed to prove a benefit, then the benefit must be small. This argument displays an ignorance of the data, statistics and the breast cancer problem. The fact that it may take more younger women to "prove" the same benefit, because they do not die as rapidly as older women, does not diminish the fact that, ultimately, the same percentage of lives can be saved.

Despite the fact that the trials were not designed to provide the "proof" that NCI is requiring, and were not optimized for women ages 40-49, the trend toward benefit is clear. Five out of the 7 non-Canadian trials demonstrate decreased mortality for women screened under the age of 50. The Canadian trial has been severely criticized for its design and performance. Even Canadian epidemiologists have recently recommended that, because of the problems with the trial, the data should not be used to alter any screening recommendations. When the other seven trials are reviewed, the direction is clear. There was a 23% mortality reduction for younger women in the HIP trial, and a similar reduction for women in the Edinburgh trial. The Kopparberg trial has shown a 24% reduction in breast cancer deaths for women under the age of 50 and the Malmo trial now has a 49% reduction with Goteborg recently reporting a 40% reduction in breast cancer deaths for these women. I have been unable to obtain the most recent data from Stockholm, but I understand that this trial is also beginning to show a benefit. In fact, the only non-Canadian trial that has not shown a benefit is the Ostergotland trial. In that trial, more than 50% of the women who died from breast cancer in the screened group, had actually refused to be screened, although they are included in the data analysis as having been screened. The NCI analysts have ignored these results, and dismissed them as not statistically significant, despite the fact that they know the trials lack the power to provide significance. Despite the fact that at least 5 out of the 7 trials show a benefit, the NCI analysts have stated that these benefits do not even suggest a trend.

The NCI should not have used sub-group analysis in the first place to analyze the data from these trials to make medical recommendations. Since they have used inappropriate sub-group analysis and weakened the power of the trials, they should not ignore the obvious trends in the data. If the non-Canadian trial data are analyzed according to the way the trials were actually designed, there is a mortality reduction that is statistically significant for screening women ages 40-74.

Not only do the randomized, controlled trials indicate a benefit, but there are data from other studies that clearly show that there is no difference in the benefit for women ages 40-49 as compared to women ages 50-59. Since the NCI has decided to use the randomized trial data in a statistically inappropriate fashion, they cannot legitimately dismiss the results from these other studies.

In addition to flawed statistical analysis, much confusion has arisen from the pronouncements of those who know little about mammography. There is a general lack of understanding of the use of mammography among those who have analyzed the data at the NCI. They seem to believe that mammography is beneficial for women who already have a lump, but not for early detection. The scientific fact is that the only efficacy for performing any kind of examination of the breast is to try to find a cancer earlier so that the woman may have an improved chance for survival, and have her breast spared. This is the only scientifically valid reason for a clinical breast examination, and the only scientifically valid reason for mammography. In fact, the only efficacious reason for doing mammography at all is to detect a cancer before it can be felt not after it has become detectable by clinical examination as those at the NCI incorrectly believe.

There is a common mythology that has been promulgated by the NCI analysts that the breasts of younger women are dense, and hide early cancers which then become evident when the breast turns to fat at the age of 50. This is simply incorrect. There is nothing magical that happens to the breast as seen by mammography at age 50, or even at menopause. Modern mammography has been shown to be able to detect small cancers among women ages 40-49 at an equal rate to that found for women ages 50-59. In our own practice we are able to detect early breast cancers regardless of age. In our published analysis of women under the age of 50 whose cancers were detected by mammography alone, the five year survival rate was 95% while women who had not had mammograms and presented with palpable lumps had only a 74% five year survival.

The NCI has not only incompletely interpreted the scientific evidence, but their new recommendations are completely inconsistent. They have suggested that recommendations should only be made based on proof of efficacy from randomized, controlled trials. Nevertheless, they suggest that clinical breast examination continue to be performed. The only efficacious reason for performing a clinical breast examination is to screen to detect breast cancer earlier. If the NCI will not accept the evidence supporting screening mammography, there are no data that support the use of clinical breast examination for women ages 40-49. The NCI has somehow overlooked the fact that the Canadian Screening program, that NCI has used to withdraw support for mammography screening for women ages 40-49, also failed to show a benefit from clinical breast examination among these women.

NCI has also suggested that high risk women continue to be screened. If the data supporting screening all women ages 40-49 are not acceptable, the NCI should be aware of the fact that there are absolutely no data that show that screening high risk women will result in fewer deaths. Screening women at high risk (depending how risk is defined) will provide a higher yield of cancers per thousand women screened, but what NCI fails to acknowledge is that more than 60-95% of breast cancers develop in women who are not at any increased risk. Thus, screening only high risk women will miss the majority of breast cancers.

If scientific analysis is applied consistently, the evidence supports screening all women beginning by age 40. If the NCI approach to the data is used, there is no justification for

any form of breast evaluation for any woman under the age of 50. The NCI approach is incorrect.

The inconsistency and incongruity of the NCI position is reflected in the fact that the Director of the National Cancer Institute, while withdrawing support for screening women ages 40-49 has stated, with regard to his own patients:

> "What I would do as an individual is recommend annual mammograms, but I can't recommend it to the public because I don't have the facts." (1)

Unfortunately, having invested its prestige in this controversy, it is unlikely that the NCI will alter its position. I do agree with the Institute's recommendation that women and their physicians be fully informed. The NCI should adhere to its own insistence on full-disclosure. Although I would prefer that the revised guidelines be withdrawn, as a minimum the following should be added:

> "Women and physicians should be aware that other experts interpret the available data as suggesting a benefit for the mammographic screening of women ages 40-49 that is similar to that for women ages 50-59. Experts have pointed out that the data reviewed come from trials that lack the statistical power to provide statistically significant results. Nevertheless, there is a trend toward benefit that has been seen in at least 5 out of the 8 screening trials."

Many believe that the NCI decision was made to avoid the politically difficult discussion of resource allocation. As a scientific body, the National Cancer Institute should clearly separate scientific and medical from economic analysis. The Institute should provide the best medical advice without regard to the economics. "Society" can then determine what is affordable.

There was no compelling reason to change the guidelines with the exception that women ages 40-40 should be screened every year, not every two years. New methods of breast analysis are being explored, but it is unlikely that they will replace screening with mammography. It is unlikely that ultrasound will ever be useful for screening. Magnetic resonance imaging may be helpful in selected situations, but will not likely be applicable to general screening due to, among other problems, accessibility, high cost, and the need for the intravenous administration of contrast material. Other imaging techniques including nuclear medicine scanning, transillumination, and immunoimaging have thus far been disappointing and are unlikely to replace mammography screening.

The NCI analysis has ignored the preponderance of scientific evidence that strongly suggests a benefit for screening women at least beginning by age 40 and on an annual basis. Earlier detection can reduce mortality and permits less disfiguring and less aggressive modes of therapy. There is not one among us who does not know of a woman diagnosed with breast cancer while in her forties, and many at a younger age. Before these women are abandoned we should remember that in 1993 there were 28,900 women ages 40-49 who were diagnosed with breast cancer. This is only 8% fewer than the 31,500 cancers diagnosed among women ages 50-59. Virtually the same percentage of breast cancers occur among women ages 40-49 (16%) as among women ages 50-59 (17%). We should not lose sight of the fact that at least 40% of the years of life lost to breast cancer are among women diagnosed before the age of fifty. Women and their physicians should be provided with all this information.

Proponents of screening have no illusions that mammography is the solution to the problem of breast cancer. Clearly increased research is needed to discover ways to prevent

breast cancer, or to devise a universal cure, but until those are found, the major hope for women lies in annual screening with mammography and physical examination beginning by age 40.

Thank you for giving me the opportunity to discuss these issues with you.

Daniel B. Kopans, M.D.

Mr. TOWNS. Thank you. Thank you very much for your testimony.

Dr. Cantwell.

STATEMENT OF KATHLEEN G. CANTWELL, M.D., CONSULTANT FOR BREAST AND CERVICAL CANCER PROJECT, ON BEHALF OF THE NATIONAL MEDICAL ASSOCIATION

Dr. CANTWELL. Thank you, Chairman Towns. Good afternoon, Chairman Towns and subcommittee members. I am Kathleen Cantwell, a practicing radiologist in the metropolitan Washington area.

On behalf of the National Medical Association, NMA, an organization representing more than 20,000 African American physicians, I appreciate this opportunity to testify on the National Cancer Institute's revised mammography screening guidelines and what they mean for African American women and our physician population.

NCI's recently revised mammography guidelines have added substantially to the confusion about breast cancer screening in the United States. The explanation for revising the guidelines is that the randomized studies don't show statistically significant reduction in mortality rates as a result of screening mammography, yet the majority of studies cited do suggest a mortality decrease for screening in the 40 to 49 age group.

The current estimates predict that nearly 2 million women in the United States will be diagnosed with breast cancer in the 1990's and 460,000 of these women will die from their breast cancers. Of these cancers, 17 to 20 percent will be in the age group of 40 to 49.

The incidence and the mortality rate of breast cancer for this age group is higher in African American women than in white women. The NMA encourages and endorses physician and patient communication, feedback, and joint decisionmaking; however, the proposed recommendation for individualization of screening for women 40 to 49 taking into effect risk factors is problematic since the majority of these patients have no risk factors. Eighty percent of women who develop breast cancer in this country have no known or recognized risk factors.

Since 1988, the National Medical Association has adopted five resolutions in its house of delegates that concern the issues relating to breast cancer: Detection; inadequacy of cancer incidence, morbidity and mortality data bases in African American women; the incidence of breast cancer among African American women below the age of 40; lack of availability and accessibility and the underutilization of screening and diagnostic mammography in African American communities; and, the differential treatment.

On the basis of these resolutions, the National Medical Association can not endorse the revised breast cancer screening guidelines of the NCI. I appear today to add NMA's voice of strong concern over screening guidelines. We must take issue with these guidelines as they affect women under the age of 50.

I also am a counselor to the American College of Radiology and I am vice chair of the radiology section of the National Medical Association. We also must take exception to any additional barrier or obstacles placed in the path of our African American women which

impact upon their death rate, their choices of treatment options, and their overall long-term survival.

As I have worked with the NMA's breast and cervical cancer screening physician education project, I have watched the efforts to educate our physicians and the public on mammography screening as they have unfolded through many focus sessions, symposia, joint projects, numerous educational projects, and many individual and group efforts. We have been in the forefront of educating our physicians and our female patients and their families to the tremendous benefits of early breast cancer detection.

The NCI has reported that between 1973 and 1993 the breast cancer incidence in African American women under the age of 50 increased 16.2 percent, compared to 5.9 percent for their white counterparts. Between 1973 and 1990, white women under the age of 50 experienced a decline of 12.5 percent in breast cancer mortality rates. African American women experienced a 2.5 percent increase in mortality.

Are we supposed to ignore these figures?

The NMA is quite concerned about the impact these revised mammography guidelines will have on underserved communities that have not yet had the opportunity to benefit from screening, diagnosis, and treatment of breast cancer, even at the levels now recommended.

We have seen progress, progress within a resistant patient population. We have slowly, painstakingly gotten the message out to a reluctant group of women, those personally affected by this devastating disease of breast cancer.

Now the NCI changes the rules. Our patients hear the turmoil. What happens to our African American women? A giant step backwards. Our patient population becomes confused and leery again and will lose much valuable progress and momentum toward our goal of early breast cancer detection.

Still not enough women of color, not enough African American women, are being screened. The biggest fears are finding breast cancer, and we do find the cancers. Our women find their breast cancers in a more advanced stage, and die at higher rates. No adequate data is available to establish screening criteria for African American women.

Until sufficient data is available in African American women, we should continue to recommend screening between the ages of 40 and 49. Until such time that there is sufficient data on the African American woman to draw different conclusions, screening starting at 40 should continue to be recommended.

Thank you.

[The prepared statement of Dr. Cantwell follows:]

National Medical Association

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STATEMENT

of the

NATIONAL MEDICAL ASSOCIATION

on

THE NATIONAL CANCER INSTITUTE'S REVISED MAMMOGRAPHY SCREENING GUIDELINES

Presented By

Kathleen G. Cantwell, M.D., FACR

before the

SUBCOMMITTEE

on

HUMAN RESOURCES & INTERGOVERNMENTAL RELATIONS

COMMITTEE ON GOVERNMENT OPERATIONS

MARCH 8, 1994

GOOD MORNING, CHAIRMAN TOWNS, DISTINGUISHED SUBCOMMITTEE MEMBERS.

I AM KATHLEEN CANTWELL, A PRACTICING RADIOLOGIST IN THE METROPOLITAN WASHINGTON AREA. ON BEHALF OF THE NATIONAL MEDICAL ASSOCIATION (NMA), AN ORGANIZATION REPRESENTING MORE THAN 20,000 AFRICAN AMERICAN PHYSICIANS, I APPRECIATE THE OPPORTUNITY TO TESTIFY ON NATIONAL CANCER INSTITUTE'S REVISED MAMMOGRAPHY SCREENING GUIDELINES AND WHAT THEY MEAN FOR AFRICAN AMERICAN WOMEN AND OUR PHYSICIAN POPULATION.

NCI'S RECENTLY REVISED MAMMOGRAPHY GUIDELINES HAVE ADDED SUBSTANTIALLY TO THE CONFUSION ABOUT BREAST CANCER SCREENING IN THE UNITED STATES. THE EXPLANATION FOR REVISING THE GUIDELINES IS THAT TO DATE, CLINICAL TRIALS HAVE BEEN STATISTICALLY INCONCLUSIVE THAT MAMMOGRAPHY IS A CLEAR BENEFIT OR SIGNIFICANTLY REDUCES THE MORTALITY FROM BREAST CANCER IN WOMEN 40-49 YEARS OF AGE. THE NCI STATES THAT THIS CONCLUSION FOR MAMMOGRAPHY SCREENING IN FEMALES AGE 40-49 MUST BE DRAWN FROM SCIENTIFIC EVIDENCE, AND REQUIRES THAT A RANDOMIZED STUDY SHOW STATISTICALLY SIGNIFICANT REDUCTIONS IN

MORTALITY RATE AS A RESULT OF THE SCREENING MAMMOGRAM. ALTHOUGH THE MAJORITY OF STUDIES CITED DID SUGGEST A MORTALITY DECREASE FROM SCREENING IN THE 40-49 AGE GROUP, NO STUDY HAD ACHIEVED THE CONVENTIONAL CRITERIA TO BE STATISTICALLY SIGNIFICANT.

CURRENT ESTIMATES PREDICT THAT NEARLY 2 MILLION WOMEN IN THE UNITED STATES WILL BE DIAGNOSED WITH BREAST CANCER IN THE 1990'S AND THAT 460,000 OF THESE WOMEN WILL DIE FROM BREAST CANCERS. OF THESE CANCERS 17% TO 20% WILL BE IN THE AGE GROUP OF 40-49. THE INCIDENCE AND THE MORTALITY RATE OF BREAST CANCER FOR THIS AGE GROUP IS HIGHER IN AFRICAN AMERICAN WOMEN THAN IN WHITE WOMEN.

IN DETERMINING APPROPRIATE GUIDELINES FOR THE AFRICAN AMERICAN WOMAN WE MUST FIRST REALIZE AND APPRECIATE BOTH THE PAUCITY OF DATA AND LOWER RATE OF PARTICIPATION IN THESE CLINICAL TRIALS FOR WOMEN OF COLOR. THE CANADIAN STUDY HAD A TOTAL OF ONLY 130 WOMEN LISTED AS "BLACK". THE ONLY LARGE NUMBERS OF AFRICAN AMERICAN WOMEN PARTICIPATING IN ANY STUDY IS THE NON-RANDOMIZED STUDY OF THE BREAST CANCER DETECTION DEMONSTRATION PROJECTION (BCDDP). IN THAT STUDY, OF THE CANCERS DETECTED (268 TOTAL) IN AFRICAN AMERICAN WOMEN, 48% WERE IN WOMEN UNDER AGE 50 COMPARED WITH ONLY 31% OF

ALL PARTICIPANTS.

THE OVERALL INCIDENCE OF BREAST CANCER IN AFRICAN AMERICAN WOMEN IS LESS THAN IN WHITE WOMEN. WE HAVE A GREATER MORTALITY AND THE STAGE OF DISEASE IS MORE ADVANCED AT THE TIME OF DIAGNOSIS WITH SUBSEQUENT POORER SURVIVAL. WE HAVE AN INCREASED INCIDENCE OF BREAST CANCER IN THE UNDER 45 AGE GROUP. THESE ARE COMPELLING OBJECTIVE INDICATORS THAT WE SHOULD CONTINUE TO RECOMMEND SCREENING IN THE 40 TO 49 AFRICAN AMERICAN WOMEN DESPITE THE CHANGE IN THE BROAD BRUSH NCI RECOMMENDATIONS. UNTIL SUCH TIME THAT THERE IS SUFFICIENT STATISTICAL DATA FROM STUDIES OF AFRICAN AMERICAN WOMEN TO JUSTIFY OTHER CONCLUSIONS, SCREENING STARTING AT AGE 40 SHOULD CONTINUE TO BE RECOMMENDED.

THE NMA IS GREATLY INVOLVED IN THIS ISSUE, AND HAS BEEN FOR A NUMBER OF YEARS. WE ARE THE PHYSICIANS OF AFRICAN AMERICAN WOMEN THROUGHOUT THE UNITED STATES. WE HAVE ASSUMED A PERSONAL COMMITMENT FOR IMPACTING UPON THE SURVIVAL AND HEALTH OF AFRICAN AMERICAN WOMEN.

SINCE 1988, THE NMA HAS ADOPTED FIVE (5) RESOLUTIONS IN THE ANNUAL HOUSE OF DELEGATES MEETING THAT ADDRESS CONCERNS AND ISSUES RELATED TO BREAST CANCER: 1. DETECTION; 2. THE INADEQUACY OF CANCER INCIDENCE, MORBIDITY AND MORTALITY DATA BASES IN AFRICAN AMERICANS; 3. THE INCIDENCE OF BREAST CANCER AMONG AFRICAN AMERICAN WOMEN LESS THAN 40 YEARS OF AGE; 4. BOTH THE LACK OF AVAILABILITY AND ACCESSIBILITY AND UNDERUTILIZATION OF SCREENING AND DIAGNOSTIC MAMMOGRAPHY IN AFRICAN AMERICAN COMMUNITIES; AND 5. DIFFERENTIALS IN TREATMENT. ON THE BASIS OF THESE RESOLUTIONS, THE NMA COULD NOT ENDORSE THE REVISED BREAST CANCER SCREENING GUIDELINES NOW UNDER CONSIDERATION BY THE NATIONAL CANCER INSTITUTE.

THE NMA ENCOURAGES AND ENDORSES PHYSICIAN AND PATIENT COMMUNICATION, FEEDBACK AND JOINT DECISION MAKING. HOWEVER, THE PROPOSED RECOMMENDATION FOR INDIVIDUALIZATION OF SCREENING FOR WOMEN 40-49, TAKING INTO ACCOUNT RISK FACTORS IS PROBLEMATIC WHEN PHYSICIANS WILL NOT HAVE SUBSTANTIVE INFORMATION FROM EPIDEMIOLOGIC SURVEYS TO SHARE WITH THEIR PATIENTS. THE VAST MAJORITY OF WOMEN WITH BREAST CANCER HAVE NO RISK FACTORS AT ALL. AN ABSENCE OF EVIDENCE IS NOT THE SAME AS A DEMONSTRATION OF LACK OF EFFECT. WE ADVOCATE THAT BIO-SOCIAL RISK FACTORS BE CONSIDERED OR UTILIZED AS A RATIONALE FOR ASYMPTOMATIC BREAST CANCER

SCREENING WITH MAMMOGRAPHY IN AFRICAN AMERICAN WOMEN. HOW WILL PROFESSIONAL EDUCATION PROGRAMS THAT ARE VOLUNTARILY UNDERTAKEN, AS WELL AS FEDERALLY FUNDED PROGRAMS, RESOLVE THE ISSUE OF SCREENING IN WOMEN LESS THAN 50, WHEN THE SUMMARY OF FUTURE RESEARCH DIRECTIONS IN THE REPORT OF THE INTERNATIONAL WORKSHOP STATES; "IT IS UNLIKELY THAT LARGE RANDOMIZED CLINICAL TRIALS ON THIS QUESTION WILL BE MOUNTED ELSEWHERE IN THE WESTERN WORLD"? MORE EXPLICIT EXPOSITION AND SUMMARY OF THE SCIENTIFIC EVIDENCE MUST BE MADE AVAILABLE TO PHYSICIANS AND OTHER HEALTH CARE PROVIDERS.

NMA IS CONCERNED WITH THE CANCER STUDIES USED BY NCI IN THE REVISION OF ITS SCREENING GUIDELINES BECAUSE THEY LACK GENERALIZATION TO SPECIAL POPULATIONS. ENOUGH DATA IS NOT YET CONCLUSIVE AS TO THE BIOLOGY OF THE DISEASE AMONG THIS SEGMENT OF THE POPULATION.

WHILE THE EVIDENCE FOR A BENEFIT FROM THE CLINICAL TRIAL DATA IN WOMEN AGED 40-49 HAS NOT BEEN AS STRONG AS THAT OBSERVED FOR WOMEN AGED 50 YEARS AND OLDER, THE AMERICAN CANCER SOCIETY AND OTHER ORGANIZATIONS FOUND THESE DATA AND THE VERY FAVORABLE PERFORMANCE OF MAMMOGRAPHY IN THE BCDDP TO BE SUFFICIENTLY COMPELLING TO RECOMMEND THAT WOMEN AGED 40-49 BE SCREENED EVERY

1-2 YEARS WITH MAMMOGRAPHY AND ANNUALLY WITH CLINICAL BREAST EXAMINATION.

THERE ARE NO ADEQUATELY DESIGNED AND CONDUCTED PROSPECTIVE RANDOMIZED TRIALS THAT CAN ANSWER THE QUESTION OF SCREENING EFFICACY IN WOMEN AGED 40-49. HOWEVER, THERE IS COMPELLING INFERENTIAL EVIDENCE THAT SCREENING CAN BE AS EFFECTIVE IN THIS AGE GROUP AS HAS BEEN MORE CONVINCINGLY DEMONSTRATED IN WOMEN AGED 50 YEARS AND OLDER.

THE NATIONAL STRATEGIC PLAN FOR THE EARLY DETECTION AND CONTROL OF BREAST AND CERVICAL CANCERS SPEAKS TO THE LACK OF INTEGRATION AND COORDINATION OF THE ELEMENTS VITAL TO THE SUCCESS OF ANY EARLY DETECTION AND CONTROL PROGRAM. THE LANGUAGE OF THE PLAN STATES FURTHER; " NO SYSTEMATIC PROCESS IS USED TO MONITOR THESE ELEMENTS TO ENSURE THAT THEY ARE CONTRIBUTING TO THE PROCESS AND ARE FULLY COORDINATED WITH THE OTHER ELEMENTS." CONSENSUS GUIDELINES ARE JUST ONE ELEMENT AND THE NMA ARGUES STRONGLY THAT ANY CONSIDERATION OF CHANGE AT THIS TIME BE REVIEWED IN THE BROADEST POSSIBLE PROGRAM PERSPECTIVE, AND WITH SPECIFIC ATTENTION TO GOALS

AND OBJECTIVES FOR BREAST CANCER MORTALITY AND MORBIDITY REDUCTION IN AFRICAN AMERICAN WOMEN.

I APPEAR TODAY TO ADD NMA'S VOICE OF STRONG CONCERN OVER MAMMOGRAPHY SCREENING GUIDELINES PROFFERED BY NCI. WE MUST TAKE ISSUE WITH THESE GUIDELINES AS THEY AFFECT WOMEN UNDER THE AGE OF 50. AS A COUNCILLOR TO THE AMERICAN COLLEGE OF RADIOLOGY, AS FOUNDING CHAIRPERSON OF THE WOMEN PHYSICIANS SECTION OF THE DISTRICT OF COLUMBIA MEDICAL SOCIETY AND ITS EFFORTS TO PROMOTE BREAST CANCER SCREENING IN DC, AS VICE CHAIR OF THE RADIOLOGY SECTION OF THE NMA, I MUST TAKE EXCEPTION TO ANY ADDITIONAL BARRIER OR OBSTACLES PLACED IN THE PATH OF OUR AFRICAN AMERICAN WOMEN WHICH IMPACT UPON THEIR DEATH RATES, CHOICES OF TREATMENT OPTIONS AND OVERALL LONGTERM SURVIVAL.

AS A CONSULTANT TO THE NMA'S BREAST AND CERVICAL CANCER SCREENING PHYSICIAN EDUCATION PROJECT, I HAVE WATCHED THE EFFORTS TO EDUCATE PHYSICIANS AND THE PUBLIC ON MAMMOGRAPHY SCREENING UNFOLD. THROUGH FOCUS SESSIONS, SYMPOSIUMS, JOINT PROJECTS, NUMEROUS EDUCATIONAL PROJECTS AND MANY INDIVIDUAL AND GROUP EFFORTS, WE

HAVE BEEN IN THE FOREFRONT OF EDUCATING OUR PHYSICIANS AND OUR FEMALE PATIENTS AND THEIR FAMILIES TO THE TREMENDOUS BENEFITS OF EARLY BREAST CANCER DETECTION.

THE NCI HAS REPORTED THAT BETWEEN 1973 AND 1993, THE BREAST CANCER INCIDENCE IN AFRICAN AMERICAN WOMEN UNDER THE AGE OF 50, INCREASED 16.2% COMPARED TO 5.9% FOR THEIR WHITE COUNTERPARTS. BETWEEN 1973 AND 1990, WHITE WOMEN UNDER THE AGE OF 50 EXPERIENCED A DECLINE OF 12.5% IN BREAST CANCER MORTALITY RATES; AFRICAN AMERICAN WOMEN EXPERIENCED A 2.5% INCREASE IN MORTALITY. ARE WE SUPPOSE TO IGNORE THESE FIGURES.

THE NMA IS QUITE CONCERNED ABOUT THE IMPACT THESE REVISED MAMMOGRAPHY GUIDELINES WILL HAVE ON UNDERSERVED COMMUNITIES THAT HAVE NOT YET HAD THE OPPORTUNITY TO BENEFIT FROM SCREENING, AND DIAGNOSIS AND TREATMENT OF BREAST CANCER EVEN AT THE LEVEL UP TO NOW RECOMMENDED.

WE HAVE SEEN PROGRESS, PROGRESS WITHIN A RESISTANT PATIENT

POPULATION. WE HAVE SLOWLY, PAINSTAKINGLY, GOTTEN THE MESSAGE OUT TO A RELUCTANT GROUP OF WOMEN, THOSE PERSONALLY AFFECTED BY THIS DEVASTATING DISEASE - BREAST CANCER. NOW THE NCI CHANGES THE RULES. OUR PATIENTS HEAR THE TURMOIL. WHAT HAPPENS TO OUR AFRICAN AMERICAN WOMEN? A GIANT STEP BACKWARDS. OUR PATIENT POPULATION IS CONFUSED, AND LEERY TO BEGIN WITH, WE LOSE MUCH VALUABLE PROGRESS AND MOMENTUM TOWARD OUR GOAL OF EARLY BREAST CANCER DETECTION.

EVEN TODAY MOST CANCERS ARE FOUND BY PATIENTS THEMSELVES, THROUGH BREAST SELF-EXAMINATION. OTHERS ARE FOUND THROUGH PHYSICIAN EXAMINATION. MOST TUMORS FOUND BY PALPATION ARE AT LEAST 2CM IN SIZE AND AT THAT SIZE THE SURVIVAL RATE IS ONLY 55%. MAMMOGRAPHY FINDS SMALLER TUMORS AND MUCH EARLIER, WHEN THE 5 YEAR SURVIVAL RATE APPROACHES 95%. MAMMOGRAPHY IS THE KEY TO EARLY DETECTION AND THUS IMPROVED LONGTERM SURVIVAL.

STILL NOT ENOUGH WOMEN OF COLOR, NOT ENOUGH AFRICAN AMERICAN WOMEN ARE BEING SCREENED. THE BIGGEST FEARS ARE OF FINDING BREAST CANCER. AND WE DO FIND THE CANCERS. OUR WOMEN FIND THEIR BREAST CANCERS AT A MORE ADVANCED STAGE AND DIE AT HIGHER RATES. NO

ADEQUATE DATA IS AVAILABLE TO ESTABLISH SCREENING CRITERIA FOR AFRICAN AMERICAN WOMEN. UNTIL SUFFICIENT DATA IS AVAILABLE IN AFRICAN AMERICAN WOMEN, WE SHOULD CONTINUE TO RECOMMEND SCREENING BETWEEN THE AGES OF 40 -49.

UNTIL SUCH TIME THAT THERE IS SUFFICIENT DATA ON THE AFRICAN AMERICAN WOMEN TO DRAW DIFFERENT CONCLUSIONS - SCREENING STARTING AT 40 SHOULD CONTINUED BE RECOMMENDED.

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Mr. TOWNS. Thank you very much, Dr. Cantwell. Dr. Gerard.

STATEMENT OF DAVA F. GERARD, M.D., BREAST CANCER SURGEON, SUSAN G. KOMEN BREAST CANCER FOUNDATION

Dr. GERARD. Thank you. I'm Dr. Gerard. I am a breast surgeon. I have been practicing in Orange County, CA, for the last 14 years and I am here as a representative of the Susan G. Komen Breast Cancer Foundation.

This is an organization that was founded by Nancy Brinker, who chaired the President's Special Commission on Breast Cancer. The Komen Foundation has the mission of eradicating breast cancer as a life-threatening disease by advancing research, education, screening and treatment. It does this through a vertically oriented organization effective in 48 States through either Race for the Cure events, or through our chapter network.

We, at the Komen Foundation, have really worked long and hard for broadening the mammography guidelines and would like to voice our support to the Congressional Caucus for Women's Issues in their efforts to provide this as an amendment to the health care reform.

I think it's important today to step back. And I'm a clinical person. I am not a researcher but I am trained in evaluating epidemiologic studies and at reviewing statistics and translating this into clinically revelant information. This is my job: translating this information for the patients.

And in the long hours that I spent not only reviewing the data but also reviewing the comments of Dr. Kopans you have to sit there and go through those studies and see that, in fact, in the Canadian study these women were not randomized until after they had a clinical examination so what we had was a screening group that, in fact, had many, many more advanced cancers than a control group.

The control group looked like it did great—there were very few breast cancer deaths. The screening group looked like it did poorly—there were many breast cancer deaths. And it looked this way because at the start of the study there was not truly a randomization of the women. This is a very, very significant flaw which effectively renders the much-publicized conclusions of the study invalid.

There are additional problems. There were women that went out and—who were in that control group and had screening mammograms on their own. If we looked at the Swedish studies, about 35 percent of the Swedish women who were in their control groups went off and had mammograms on their own. This was also a factor not considered in the Canadian study. I can go on with several other flaws but there are some very, very major flaws and I really think it's really outrageous that we should gloss over them as if they're not important. They are very important.

And what those flaws, in fact, do or have done by glossing over them is provide reason for some individuals who have a bias that we should not be screening young women, to recommend against screening them. This is wrong and I think the clinicians out in the real world know that this is wrong. And certainly the breast surgeons who are really the people that are there talking to the

women when they are diagnosed with breast cancer know that this is not correct.

For breast surgeons, when we have, unfortunately, to tell a woman she has breast cancer, we can often temper the anxiety and the fear by explaining to the woman it's an early breast cancer if, in fact, it is so, and that, really, her chances of surviving this disease are really quite good.

It's important for us to be able to realistically provide this hope to a patient and for the facts to be correct. It's important for health care professionals like myself to have the opportunity to exchange information with the policymakers and let them know that these policies have significant impact on "real people." These are not just numbers. These are not just policies that need to satisfy scientists. There are real women there who are dying of this very real disease.

I became involved in the Komen Foundation when it became very clear to me, as a breast surgeon, that there were issues that I could not take care of in the operating room—that's a big statement for a surgeon to actually say—but, in fact, there are psychosocial issues that prevent women from being screened. There are psychosocial issues that deal with the quality of life when a woman is diagnosed and undergoing treatment for breast cancer..

There are a number of us in Orange County who are breast cancer professionals who volunteered our time, along with the assistance of breast cancer survivors, with the assistance of probably some of the most effective women leaders in our community, and we started a number of programs, including, for example, Komen Kids, which is a support group for children who have a parent with cancer. Breast cancer is not only a disease of women. These women have families: They are mothers, they are sisters, they are daughters, and they are wives.

Komen Kids is now a national program. We then formed Karen's Kids. Karen was a 43-year-old woman who died of breast cancer about 6 weeks ago. Her 10 and 12-year-old sons told us they needed a grieving group for children and so now we have Karen's Kids.

But also from our local Race for the Cure moneys we funded our own breast cancer early detection program with the purpose of getting out there into the communities of women who had limited resources, of minority women, of women who had difficulty accessing our health care institutions.

With the race funds we were able to provide 1,000 women with an early detection program in our first year. We include clinical breast examination, screening mammograms, and BSE instruction in the program. In the first year we found eight women with breast cancer. Three of those eight women were under the age of 50. Two of the three have early breast cancers. And I ask this group: Did this early detection program save these women's lives? That's the question that we're really being asked.

Now, in summary, I would like to say that the Komen Foundation very strongly supports the guidelines that recommend screening mammograms for women under the age of 50, between 40 and 50, every 1 to 2 years, and clinical breast examination every year.

And I think what you are hearing from this consensus of health care professionals who actually function out in the real world, is that we need to have these guidelines. And with the NCI coming

out and issuing a change, the wrong message is being sent, and that message is going to spill over into our 50 to 59 year old and 60 to 69 year old women who we know conclusively, beyond a shadow of a doubt, that we can help prevent deaths from breast cancer.

And I hope that this group will very seriously consider the implications of the change in the guidelines. There are very real women whose lives are at stake in these considerations.

Thank you.

[The prepared statement of Dr. Gerard follows:]

TESTIMONY OF DAVA F. GERARD, M.D.
ON BEHALF OF
THE SUSAN G. KOMEN BREAST CANCER FOUNDATION
NATIONAL MEDICAL ADVISORY PANEL
ON
MARCH 8, 1994
BEFORE THE
HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS
SUBCOMMITTEE
HOUSE GOVERNMENT OPERATIONS COMMITTEE
UNITED STATES HOUSE OF REPRESENTATIVES

Mr. Chairman, and members of the Subcommittee, I am Dr. Dava Gerard, a breast surgeon in private practice for fourteen years in Orange County, California. I am testifying on behalf of the Susan G. Komen Breast Cancer Foundation, a thriving vertically-integrated organization that works at the national, state and local levels to eradicate breast cancer as a life-threatening disease by advancing research, education, screening and treatment. Founded in 1982 by Nancy Brinker in memory of her sister Susan G. Komen, the Foundation is a national network of volunteers working through local chapters and RACE FOR THE CURE events now in 48 cities, representing 30 states and the District of Columbia. Central to Komen's program is meeting the needs of the underserved, minorities and those least able to access health care.

I want to take this opportunity on behalf of the Komen Foundation to thank Chairman Towns for his energetic commitment to the fight against breast cancer, and particularly for the recent introduction of his Sense of the Congress Resolution that mammography screening should be made available for women under the age of 50 -- a position we strongly endorse!

In my testimony today, I will present my own review of the scientific evidence upon which the National Cancer Institute based the decision to eliminate its mammography guideline for women 40 to 49, and will briefly summarize my professional judgment regarding the benefits of mammography screening for women in this age category. I will also highlight the efforts of the Orange County, California Chapter of the Susan G. Komen Breast Cancer Foundation to fight breast cancer.

Validity of Scientific Trials Considered by NCI in Mammography Guidelines Review

Eight randomized clinical trials, including the National Breast Screening Study ("NBSS") of Canada, were reviewed by the NCI Workshop on Breast Cancer Screening in its effort to determine if routine screening mammography resulted in a significant reduction in mortality for women under the age of 50. The non-Canadian controlled studies suffered from serious shortcomings. These studies lacked prospective trial design and included insufficient numbers of 40 to 50 year old women to glean statistically significant information on this age group.

Moreover, each of the randomized studies were subject to serious deficiencies. The HIP trial used unquestionably obsolete mammographic equipment of the 1970's. The Swedish trials used only single view mammography (known to miss 10% of breast cancers), provided screening at two year intervals (instead of one), and did not include a clinical breast exam. The Edinburgh trials were marred by poor compliance (only 60% of the women in the screened group had an initial screening mammogram), technical problems in their early studies, and only biannual screening. Additional concerns that mammography experts voiced about these studies were (1) the delays in investigating mammographically suspicious lesions, (2) the uncertain ascertainment of the control group deaths, and (3) major randomization problems.

The Canadian Study, or NBSS, has many significant limitations that have been de-emphasized by the Breast Cancer Screening Workshop, NCI and the press. A major design flaw was the lack of blind randomization of women into screening and control groups. Symptomatic women were permitted to participate and were assigned to the control or screened groups after clinical breast examination. Women with advanced breast cancer were assigned more frequently to the screened group. Thus there was a very high initial incidence of advanced cancers in the screened group, virtually guaranteeing an excessively high mortality rate in the screened group from the very start of this study. The control group had an unexpectedly high survival rate of 90% as compared to an expected rate of 76%. With this combination of high mortality rates (because women with advanced cancers were placed in the screened group) and unusually low mortality rates in the control group, there would have to be almost no breast cancer deaths in the screened grouping in order to demonstrate a statistically significant mortality reduction in women who were screened.

A second major design flaw in the Canadian study was that the trial did not take into consideration women who "crossed over", that is, women who were counted as members of the control group but who received mammograms outside of the trial. (In another of the 8 studies relied upon by NCI, the Malmo study, 35% of women ages 40-50 in the control group had mammograms outside the study.) Additionally, the quality of the mammograms in the Canadian NBSS has been questioned because there was no special training for either the radiologists or the technologists. Some 5% of the mammograms in years 1-4 were externally reviewed and were considered poor or unacceptable. An internal review by the NBSS project's reference radiologist showed problems with interpretations in that 42% of interval cancers were seen retrospectively and 17% of screening detected cancers were seen on mammograms taken 2-5 years previously. Furthermore, 25% of women with mammographically suspicious masses, for whom biopsy was recommended, did not undergo tissue diagnosis. This raises the question whether a delay in diagnosis could account for some of the excess mortality.

Given the serious limitations in study design and clinical research which distinguish the clinical trials reviewed by the NCI Workshop on Breast Cancer Screening, I question the appropriateness of retreating from the screening guideline for women 40 to 49 without scientifically conclusive evidence. In 1989, the NCI and twelve organizations reached a consensus that women between ages 40 and 49 should be screened for breast cancer by

mammography. Yet in eliminating the guideline the NCI made a unilateral decision, without the agreement of the breast cancer community. Moreover, in the intervening years between the adoption of NCI's original consensus guideline and its recent decision to retreat from its screening recommendation for women 40 to 49 nothing has changed! No new studies support this change.

Benefits of Mammography for Women under 50

In the United States, approximately 29,000 white women and 4,200 black women between the ages of 35 and 50 will be diagnosed with breast cancer each year. The American Cancer Society estimates are that about 30,000 women ages 40 to 49 will be diagnosed with breast cancer in 1994, and 30,000 in the 50 to 59 age group. Other estimates are that 6% of breast cancers occur in women under the age of 40, and 16% occur in women between 40 and 50. This incidence rate is not insignificant. Nor are the lives of the women diagnosed with breast cancer who are under 50. Any of these women could be our sisters, daughters, wives, friends, or even ourselves.

What is the strongest case that could be made that mammography screening benefits women who are 40 to 49 years old? The findings are at best inferential. Though we lack a scientifically conclusive answer, the inferential data must not be ignored! Four of the five studies with ten-year follow-up show approximately a non-statistically significant 20% reduction in breast cancer mortality in women ages 40 to 50. There is intermediate data from both British Columbia and the University of California at San Francisco that substitutes strong predictors for mortality, for example, tumor size and involvement of lymph nodes. In both studies the benefit of mammography is equal in the 40 to 50 year old woman and in the 50 to 70 year old woman.

The repercussions are enormous of the NCI's decision to eliminate its recommendation that women 40 to 50 receive mammography screening. The ongoing public debate has caused considerable public confusion among women and their physicians. Sadly, this much publicized change in screening guidelines creates even greater disincentives to those women who we know conclusively will benefit from mammography.

The Susan G. Komen Breast Cancer Foundation and other public and private organizations have fought over the past decade to educate women over 40 about the importance of mammography screening and breast health. Much time, effort, energy and money have been spent to break down barriers to mammography screening, especially for medically underserved women. With the change in the NCI guidelines and the resulting confusion, these barriers are being raised again. I fear we will see an increase in breast cancer mortality rates as women once again retreat from screening programs because of fear, because their insurance companies now have an excuse to deny coverage, and because health care planners under strict economic scrutiny have been pressured to advocate delay in screening in young women until we accumulate a statistically significant number of young women dead from breast cancer. I take care of these women and their devastated families. I know the suffering women and their kids

who valiantly have formed support groups like Komen Kids and Karen's Kids, which I describe at the end of my testimony. These are living, breathing people. They are not statistics to me; their suffering is very real.

As a clinician, I have much first hand experience in the enormous tragedy of this disease, but I also have much experience in creating programs designed to meet the needs of our women and their families and the community in which we all live. I fear that we have allowed individuals, "experts", to take a very one sided look at this screening issue. I fear that it will be the mammographers, breast surgeons, oncologists, radiation therapists, breast cancer support leaders, hospice professionals, children and families who will be witness to the grave error of eliminating consensus guidelines, long before "definitive" studies are completed and the statisticians have run the numbers again.

I ask this Committee to take a balanced look at this screening issue and decide that the lives of our 40 to 50 year old women are worth protecting, even before the studies have reached statistical significance.

Study Design Issues

We cannot wait ten or more years to determine if young women will benefit from state-of-the-art screening mammography. Case control studies need to be investigated, and if these studies are not appropriate, then we need a randomized prospective controlled study designed with adequate numbers of women using state of the art technology to evaluate the optimal periodicity of screening in relation to age, the relative utility of clinical breast examination and breast self- examination. Areas of research should include feasibility of digital mammography, large data banks, stereotactic fine needle and core biopsy. We need to stop pretending that many of these issues related to screening are not economically based. Research should focus on how best to deliver high quality screening programs in a cost efficient manner.

Physician Training Issues

In the United States, our physician base is not well trained in quality clinical breast examination. Studies have documented that the average length of a breast examination is 1.83 minutes and that 75% of breast exams fail to use two positions. In women 40 to 49, clinical breast exams identify 10% to 25% of the breast cancers, while combined mammography and breast exam identify between 36% and 53%. The Canadian Study consistently documents superior clinical breast examination as compared to other studies. It is clear that mammography and quality clinical breast examination are complementary screening procedures; one does not replace the other.

We know that most women, regardless of age, will be seen by a physician in any given year. We must start training our medical students, physicians and nurses to perform competent quality breast examinations. First, we must develop programs that will effectively provide this

instruction. Second, the Congress should consider proficiency certification in the basic clinical examination, much like the American Heart Association certifies basic life support proficiency.

Our primary care physicians need to be convinced that knowing how to conduct proper breast examinations and to understand mammograms are as important as how to understand chest x-rays and listen to lungs. We need to learn how to motivate our physicians. We should have done this a decade or two ago. In this decade, we will have 1.5 million women diagnosed with breast cancer and 500,000 women will die from this disease. There are plenty of opportunities to learn to perform a quality breast examination or understand a mammogram report. There is not a moment -- or another life -- to lose.

Orange County Chapter of the Susan G. Komen Breast Cancer Foundation

As a breast surgeon, I speak frequently to community and professional organizations about the importance of early detection. I pride myself in maintaining a sensitivity to patient needs. Yet became very apparent to me several years ago that the most challenging breast cancer problems occurred outside my operating room. (This is a tough statement from a surgeon.) Three years ago the Orange County, California, Chapter of the Susan G. Komen Breast Cancer Foundation was organized by several caring and committed volunteer breast cancer health care professionals, inspiring and energetic breast cancer survivors, and resourceful and experienced community leaders. Our very successful 1992 and 1993 Orange County RACE FOR THE CURE raised $500,000 through corporate sponsors, pledges and entry fees; 25% of the funds were our community's contribution to the National Komen Breast Cancer Research Fund, and 75% remained locally to fund our Orange County projects. Our chapter's collective sensitivity to breast cancer issues allowed us to develop programs rapidly and effectively, many of which became nationally available within the first year.

One example is the idea developed by 12 year-old Jon Wagner-Holtz whose mother was diagnosed with breast cancer. Jon came to us with a proposal for a children's friendship network, recalling: "When my mother got breast cancer, my mother got treated, but really my whole family got breast cancer". Jon helped organize Komen Kids, a support program for children with a parent with cancer. The program rapidly attracted several hundred young members. After the death of our first Komen Kids' mom, 42 year-old Karen, at the suggestion of her nine and twelve year old sons, a special grievance group, Karen's Kids, was added. Several Komen Kids programs have already sprung up around the country to meet this previously unaddressed need.

To explore the psychosocial issues of breast cancer, our Komen Chapter underwrote a professional interactive drama, EVERY PART OF ME, produced by STOP-GAP and performed in board rooms, conference centers and cafeterias in corporations, clinics and community centers throughout Southern California. Our national touring multimedia museum exhibition focusing on breast cancer, "MEMORIES, MILESTONES AND MIRACLES," visually documents the physical and psychological challenges of breast cancer as seen through the eyes, hands and minds of noted artists and poets.

Although this is just a sampling of programs that we developed in order to resolve unmet needs, the project of greatest interest today is our Orange County Komen RACE FOR THE CURE Breast Cancer Early Detection Program which provides language-appropriate breast self-examination instruction, clinical breast exam and ACR-approved screening mammograms to women of limited resources over the age of 40. We have just completed our 1000th screening. Approximately 50% of our screenees are under age 50. Of the 8 women identified with breast cancer, 3 were in the 40 to 49 age group. One woman had pre-invasive (in situ) breast cancer; one woman was identified by mammography only, and one woman had a breast cancer that was readily palpable once the mammographic abnormality was seen.

Conclusion

Thank you for your time and attention as we all try to compress hundreds of hours of reviews on this critical issue into a few short minutes. Mr. Chairman, you and your Subcommittee on Human Resources are playing a very critical role in the lives of our 40 to 50 year-old women. I am sure that you will consider this fact as you weigh the testimony that you have heard today. Please help us continue to advance compliance in our breast cancer early detection programs so that we do not have to take two steps backward in the hope of taking one step forward.

For our part, The Susan G. Komen Breast Cancer Foundation supports President Clinton's commitment to health care reform. We will work with you and other members of the House and Senate to provide mammography screening coverage for women under age 50 as part of the health care reform legislation. And, we will highlight the fine work you and your colleagues are doing on breast cancer issues during the Minority Breast Cancer Awareness Day Breakfast of Champions and Symposium with the Congressional Black Caucus and the Congressional Hispanic Caucus on April 28.

Finally, I want to thank you for this opportunity to testify, and I urge you to join us in RACE FOR THE CURE for breast cancer. One way you can do so is to urge all your colleagues to participate in our 5th Annual D.C. RACE on June 18.

Thank you.

Mr. TOWNS. Thank you all very much for your testimony.

Dr. Alley, let me ask you a question. You indicated that you have seen 45 patients under 50 that have had breast cancer?

Dr. ALLEY. Not that had just had breast cancer; that have had breast cancer found at a preinvasive stage when it really is curable. This is before the cancer cells have broken out of the ducts.

Mr. TOWNS. Right.

Dr. ALLEY. When you talk about mammograms saving lives, this is what we're talking about. You find, for instance, what we call micro-calcifications that are as small as a few grains of sand, and these are the women whose lives we really know we can save.

Mr. TOWNS. And this is over a period of how long?

Dr. ALLEY. In the past 2 years.

Mr. TOWNS. In the past 2 years? Dr. Gerard, do you have any idea of how many patients you have treated under?

Dr. GERARD. I know in the last 2 years I have treated about 320 women with breast cancer, of whom—and I have to tell you——

Mr. TOWNS. Under 50? How many would there be under 50?

Dr. GERARD. Under 50? The bias in my particular practice is toward younger women so there is a skewing of which I am aware. I saw about 293 women under the age of 50, but my practice tends to be a practice of younger women with breast cancer so I don't think it's really a fair comparison.

But of those women, about 30 percent of them had early—this is what we call in stage zero, this preinvasive form of breast cancer. These women we almost know for sure we're curing them.

The next set of women, the women with lesions that are often not palpable, the small, less than two centimeter size breast cancers, we know in those women we have a fair shot at curing them and we're looking at 10-year survivals that are probably someplace around 85 percent, so we have a fair shot.

And after that it really drops off in terms of our ability to provide long-term survival for women with breast cancer. There is no question we're seeing a lot of women, a lot of young women, with breast cancer, and I think if you talk to any breast surgeon she will tell you that over the years—and a large portion of that is because these younger women are getting screened. If we're not going to screen these women we're not going to be able to pick up their breast cancer until they are 50 or 55.

Our last early detection program lady was 41 years old, a Hispanic lady. She had three one centimeter—which is tiny—breast cancers. She had no lymph nodes involved. She had her surgery and I think we've got a good shot offering that lady a cure.

Mr. TOWNS. Dr. Cantwell, recognizing that black females in particular, seem to be more affected by NCI changing its rules, was the NMA contacted to seek your position on the guidelines?

Dr. CANTWELL. To my knowledge, the National Medical Association was not consulted on this, not asked what our input would be. Even the NCI's guidelines still recommend a screening mammogram for younger black women and their own standards also recognize the fact that there are more cancers and more severe cancers in the African American community.

But still there has been some dialog between the NMA and the NCI, but certainly not nearly enough.

Mr. TOWNS. We've got to be sending clear messages on this issue to women. When this information is not getting out then we have a real problem. Any time you have confusion around the issue like this, I mean you're talking about an area where it's just difficult enough to get information out as it is, then when mixed signals are sent, I mean I think that that really creates another problem.

So I would just hope that in the future at least, the medical associations and people involved in this process would have some input along the way.

When you look at the fact that the advisory board was overruled and this had never happened before—only time they have been overruled was twice in the same day—one begins to wonder what's going on at NCI.

Dr. Smart, you were around at NCI for a while. Would you have any comments on the NCAB overruling? Do you think the revision has anything to do with cutting costs?

Dr. SMART. I don't really believe it did have anything to do with cutting costs but I can say one thing; that is, when we developed the guidelines back in 1987 we had representatives of all the medical professions, professional groups, come together. We presented the data to them. We presented the data not only on randomized trials but also from the BCDDP, direct and indirect evidence, and this information was part of the consensus-making opinion.

The National Cancer Advisory Board is probably the closest thing that you will come to a representation of the medical profession and their opinion as it existed in 1987 and as it existed last November when the board voted not to change the guideline. In overruling the board, NCI was limiting the input to that same group, the same opinion, a clinical opinion. This was a mistake. If you don't have evidence that is significant to say mammography screening is not good, don't say anything. Do you have anything that would allow us to change? And the answer is, I don't see anything that was there that was new evidence that would cause them to change.

Mr. TOWNS. Dr. Kopans.

Dr. KOPANS. I would just like to make a comment on the process. I have observed and participated in the screening debate since the late 1970's and was a reviewer of the national breast screening study of Canada's mammograms which were called into question many years ago, even before the trial ended.

I think there were some points made earlier in terms of the Fletcher report which was a summary of the workshop held last February. That workshop was—I'll say quite bluntly—loaded.

Dr. SMART. Stacked.

Dr. KOPANS. The point is that it's conclusions were predetermined basically what the outcome of that meeting would be. I recommended—I was an invited panelist at that meeting, one of four—Dr. Smart was also another one—who were supporters of screening, and there were 17 others who were invited who were clearly opposed.

One of the members of that panel was Professor Sam Shapiro, professor emeritus from Johns Hopkins. Professor Shapiro actually had done the health insurance plan of New York study but had come out clearly against screening women 40 to 49 in previous lec-

tures, as well as in his writing. He was the second senior author in the Fletcher report summarizing the workshop results.

I recommended at the time of the workshop that a minority opinion be included in the summary of the workshop. In fact, that did not happen. We were finally—it was mentioned by Dr. Broder that Dr. Sickles and I had an opportunity to respond to the Fletcher report. I think we were given about 3 weeks before the deadline for publication of the Fletcher report to, in 2,500 words, review a paper that, as I recall, is about 14 pages in the Journal of the National Cancer Institute, so we weren't really able to respond to all the issues.

I would point out that Dr. Broder brought up that the President's panel on breast cancer is in agreement, or he was implying was in agreement, with the change in guidelines from the National Cancer Institute. I would dispute that, No. 1. The conclusion of the President's panel is not the same as NCI's. No. 2, I would point out that the President's panel initially did not even include diagnostic radiologists even though they were going to discuss issues of screening, and it wasn't until several of us wrote repeated letters that Dr. Dodd and Dr. Adler were included on the President's panel. Another person who was included on the President's panel was Professor Sam Shapiro, who also was instrumental in writing the final report of the President's panel.

So there is a little bit of overlap, shall we say, in the constitutions of the President's panel the Fletcher group and the final report with regard to screening for breast cancer. So I think that Dr. Broder bringing up the President's panel and suggesting that they agree, No. 1, I disagree with that and, No. 2, the President's panel could not have come out more strongly for screening because Professor Shapiro would not permit it and they couldn't reach an agreement so there were concessions made by those who felt on the President's panel that screening was beneficial.

Mr. TOWNS. Thank you very much, Dr. Kopans. Dr. Smart, having worked at NCI, in your opinion, do you think it was unusual for the scientific workshop last February to be chaired by scientists who had published their analysis of the trials and concluded that the guidelines should be revised?

Do you think that was a coincidence?

Dr. SMART. No, it wasn't a coincidence. It was planned. It was stacked. The deck was stacked.

Mr. TOWNS. Was that unusual?

Dr. SMART. Well, it depends upon the result you want to get. If you want to eliminate screening for women 40 to 49 then you just choose the group that are going to vote that way. They have all published that way. You know exactly what they are going to say.

But more importantly, they really wouldn't let you speak to the other side. They wouldn't let anything other than randomized trial data be heard.

Mr. TOWNS. I hope I'm wrong but, these names that you're calling who was on the other side and switched, they all were funded by NCI. I'm just looking at these names.

I'm just curious. I mean, I'm just wondering whether the authors of the workshop report were not pressured to produce a report fa-

voring revising the guidelines, in order to assure receipt of NCI funding. I hope not.

Dr. Kopans.

Dr. KOPANS. Well, what I was going to say, I'm not sure that, you know, I would go as far as to say that they were being paid off but, clearly——

Mr. TOWNS. I wouldn't either, but I see they were funded.

Dr. KOPANS. Well, they were funded. But, clearly, to take, for example, the Canadian screening trial. If an investigator in that trial who had spent $12 to 18 million funding the Canadian screening trial, I think it would be very difficult at the end of the trial to say, gee, we made a mistake; the data are invalid.

And I know there is no question there are those who will suggest that as a radiologist certainly I have a vested interest in perpetuating screening guidelines. I think I would like to get that out on the table.

First of all, I am an academic radiologist. I am paid a salary which I received whether or not I interpret mammograms, ultrasound, computer tomography. But I'll also point out that there are 30 million women in the United States who are over the age of 50, certainly more than enough work for those of us who do mammography. But I think in terms of vested interest, which you are somewhat alluding to——

Mr. TOWNS. Very much so.

Dr. KOPANS. I think we should not lose sight of the fact that there are subtle vested interests in the other direction and I think, unfortunately, that does cloud some of the interpretation of the data.

Dr. SMART. I think that one ought to say one other thing, and that is that all of these people were funded. All of these people who carry out randomized trials, that's what their business was, was randomized trials. They give no credence whatsoever to anything that isn't a randomized trial. I mean that's all they've got to speak, you might say.

Mr. TOWNS. Dr. Gerard.

Dr. GERARD. Yes, I would like to make a few points. One is that Nancy Brinker chaired the President's Special Commission on Breast Cancer and she presented that report to Mrs. Clinton. That report did not recommend changing any of the guidelines. I think that's very important because Dr. Broder made it sound like perhaps they were supporting the change. There was no support of the change of the guidelines by the special commission. Second, the Komen Foundation supports President Clinton's Health Care Security Act and is pleased that it does include screening for women over the age of 50. And, finally, we really would like to see the screening coverage broadened so that women over 40 can, in fact, be screened both clinically and mammographically.

And, finally, I would—on behalf of the Komen Foundation I would really like to thank this group for looking at these guidelines and asking these questions.

Mr. TOWNS. Thank you.

Dr. CANTWELL. I would just like to make one brief comment. You know, we are kind of caught in a double bind. Even Dr. Broder said himself that in order to have adequate data, statistically significant

data, he would only entertain randomized clinical trials, but yet he can not ethically authorize randomized trials because he can not include African American women, Hispanic women, jail populations.

When will we have the guidelines changed if he will only change them with randomized data from randomized studies? In other words, we are stuck with not screening these women who are 40 to 49.

There is no option available to these women except to consult physicians if those women are now currently consulting physicians, and I would submit that especially in the African American and other minority communities these women are underserved. They are not seeking out consultations with their physicians and I think this gets us into a real double bind in these patients, puts them at risk.

Mr. TOWNS. But here again, by changing the guidelines it makes it a lot worse.

Dr. CANTWELL. It makes it much more difficult to reach these women who are already reluctant to seek care. It sends a terrible message to women in general. Every time there is a news report about change in mammography standards, a change in the way that breast cancer screening is done, every radiology department in the country gets calls upon calls upon calls about what this means. Is your department certified?

These questions are inevitable any time there is any change so a trial balloon is sent up and it sets off a nervousness within the community of women at risk. I submit that this drastic change is going to have a very negative, detrimental impact on the lives and the well-being of women in this country, particularly in underserved communities.

Mr. TOWNS. Well, yes, Dr. Kopans.

Dr. KOPANS. Just one other point. Again, I hate to keep picking on Dr. Broder but there were a number of points that he made that seemed to be the light at the end of the tunnel. He was pointing out that we are close, we hope, to cloning or discovering what is called the BRCA–1 gene, which is a gene that indicates a very high risk for breast cancer and that molecular biology maybe will be the ultimate solution to breast cancer.

I think it's important to point out that only about 5 percent of cancers are associated with the BRCA–1 gene so even if that gene is cloned or discovered, first of all, I'm not exactly sure how we're going to do anything with it, but it's certainly not going to be the solution.

And I think, again, that having the National Cancer Institute do statistical analysis that is really not justified, subgroup analysis, breaking down larger groups into small groups and then trying to analyze the smaller groups, is fine for targeting new research but it is not appropriate for making recommendations. And if you're going to do that kind of subgroup analysis you have to be prepared to not have statistically significant results and to accept them; otherwise, you shouldn't be using those subgroups.

So the National Cancer Institute can't have it both ways: Either they are going to do statistically unacceptable things and have to then use all of the data available, or they should look at the trials

the way they were designed, and the trials do show benefit for screening women 40 to 49.

And I certainly would love to see the guidelines changed back. I doubt—well, I don't know whether that will actually happen. That will probably be incredibly confusing to the country but certainly at least provide women with all of the information and make sure that certainly underserved women have access to screening in whatever the health plan that we ultimately have in this country.

Mr. TOWNS. Well, let me thank all of you for your testimony. Before I conclude, let me say with unanimous consent I would like to insert into the record written testimony from Congressman Dan Burton, Congresswoman Barbara Vucanovich, and Dr. Nathaniel Berlin.

[The prepared statements may be found in the appendix.]

Mr. TOWNS. Because of the thousands of lives at stake, the subcommittee intends to continue monitoring this very important issue.

Without objection, the record will remain open for 14 days for additional information and testimony. That's 14 working days, to be clear just in case we run into some holidays in the process.

The subcommittee will now conclude.

[Whereupon, at 2:25 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

DAN BURTON
6th District Indiana

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March 7, 1994

Honorable Edolphus Towns
Chairman, Subcommittee on Human Resources
and Intergovernmental Relations
House Committee on Government Relations
B371 B & C Rayburn House Office Building
Washington, D.C. 20515

Dear Representative Towns:

Please accept my apology for not being able to testify in person regarding this very important subject of mammograms and mammography guidelines.

Recently my wife discovered she has breast cancer, and she will be undergoing extensive treatment to cure her of this dread disease. My wife, who is in her mid-fifties, was told by her doctor that her breast cancer could have been in her body for six or seven years or longer, as it was a slow growing type. This verifies that during her forties she probably had breast cancer which could have been detected through the use of a mammogram.

It is my strong feeling, as one who has had a loved one experience this dread disease, that mammography should be used by women in their forties as well as fifties, and that the National Cancer Institute should re-evaluate their screening guidelines regarding this issue.

Since my wife has discovered she has breast cancer, we have found a large number of women in their forties and fifties who likewise have had this disease. Had it not been for mammography and self-examination, many of these women would not have survived.

Mr. Chairman, you have my complete support in trying to get the Congress and the National Cancer Institute to do whatever is necessary to make sure that women have the opportunity to get mammograms as early as possible to make sure they can live a long and happy life.

Sincerely yours,

Dan Burton
Member of Conress

THE HONORABLE BARBARA VUCANOVICH

HEARING ON MAMMOGRAPHY GUIDELINES
HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
MARCH 8, 1994

FOR THE RECORD

MR CHAIRMAN, I APPRECIATE THIS OPPORTUNITY TO PRESENT MY VIEWS ON THE NATIONAL CANCER INSTITUTE'S REVISION OF ITS MAMMOGRAPHY GUIDELINES. I THANK YOU FOR HOLDING THIS HEARING ON THIS IMPORTANT MATTER.

I SPEAK TO THIS SUBCOMMITTEE AS A BREAST CANCER SURVIVOR AND A MEMBER OF CONGRESS. AS A BREAST CANCER SURVIVOR, I AM DISTURBED BY THE NATIONAL CANCER INSTITUTE'S REVISION OF MAMMOGRAPHY GUIDELINES, ESPECIALLY FOR WOMEN 40 TO 49. WHEN I LEARNED I HAD BREAST CANCER, I WAS OLDER -- 61 YEARS OLD. BUT I REMEMBER BEING THANKFUL TO MY PHYSICIAN FOR RECOMMENDING MY FIRST MAMMOGRAM -- THE ONE THAT SAVED MY LIFE.

AS A MOTHER, I LOOK AT MY DAUGHTERS AND BREATHE A SIGH OF RELIEF AND OFFER A THANKFUL WORD TO MEDICAL TECHNOLOGY. WITH MAMMOGRAPHY, MY DAUGHTERS MAY DETERMINE WHETHER THEY WILL FOLLOW THE SAME PATH AS THEIR MOTHER -- BEING ONE OF THE "ONE IN NINE". BUT WHAT ABOUT THOSE WOMEN WHO DO NOT HAVE BREAST CANCER IN THEIR FAMILIES (OR DO NOT KNOW THEIR FAMILY HISTORY), YET COULD STILL HAVE THE LIFE THREATENING DISEASE? SHOULD WE HOLD BACK THEIR ABILITY TO LEARN WHETHER BREAST CANCER HAS INVADED THEIR BODIES? I DON'T BELIEVE WE SHOULD, BUT THAT IS WHAT THE NATIONAL CANCER INSTITUTE IS DOING BY CHANGING THEIR GUIDELINES FROM RECOMMENDING A MAMMOGRAM EVERY ONE OR TWO YEARS TO WOMEN BEGINNING AT AGE 40 -- TO RECOMMENDING THAT WOMEN BETWEEN AGE 40 AND 49 JUST DISCUSS THE ADVISABILITY OF SCREENING WITH THEIR PHYSICIAN.

AS A CONGRESSWOMAN, I AM CONCERNED ABOUT HOW THESE CHANGES WERE INITIATED. PREVIOUSLY I HAVE APPEARED BEFORE THIS SUBCOMMITTEE WITH MY ESTEEMED COLLEAGUES CARDISS COLLINS AND PATRICIA SCHROEDER TO ASK THAT POLITICS NOT PLAY A PART IN THE REVISION OF THESE GUIDELINES. HOWEVER, I FEAR THAT IT HAS. TODAY, SCIENTISTS WILL TELL YOU THAT THE STUDIES USED BY NCI TO BASE THEIR CONCLUSIONS AND RECOMMENDATIONS WERE POORLY ORCHESTRATED. FURTHERMORE, THE STUDIES WERE COMPLETED AT A TIME WHEN MAMMOGRAPHY QUALITY WAS QUESTIONABLE -- MAMMOGRAPHY TECHNIQUES WERE UNPOLISHED AND FILM AND EQUIPMENT DID NOT MEET THE TOUGH STANDARDS OF TODAY -- LEADING TO MORE FALSE POSITIVE DIAGNOSES. QUITE FRANKLY, THE STUDIES USED DO NOT ANSWER THE QUESTIONS WE NEED ANSWERED TODAY -- INSTEAD, THEY CAME UP INCONCLUSIVE. YET WE ARE BASING OUR NATIONAL POLICY ON THESE INCONCLUSIVE STUDIES.

DURING MY TIME IN CONGRESS, I HAVE SEEN A METAMORPHOSIS OF WOMEN'S HEALTH ISSUES. CONGRESS HAS ACKNOWLEDGED BREAST CANCER AS A MAJOR THREAT TO WOMEN IN OUR NATION. FUNDS HAVE BEEN APPROPRIATED FOR RESEARCH USING BOTH FEDERAL AND PRIVATE DOLLARS. CONGRESSIONAL ACTION HAS ALLOWED THE MEDICARE PROGRAM TO OFFER MAMMOGRAPHY TESTS FOR WOMEN BENEFICIARIES. MANY PRIVATE INSURERS NOW OFFER MAMMOGRAPHY AS A STANDARD BENEFIT. BUT MOST IMPORTANTLY, WOMEN HAVE TAKEN MORE NOTICE OF THEIR HEALTH AND ARE COMPLETING SELF-BREAST EXAMINATIONS AND OBTAINING MAMMOGRAMS TO DETERMINE WHETHER THEY HAVE THIS DEVASTATING DISEASE. THE NATIONAL CANCER INSTITUTE'S ACTION IS LIKE STUFFING A BUTTERFLY

BACK INTO THE COCOON.
MR. CHAIRMAN, THERE IS NO CURE FOR BREAST CANCER. NO CURE AT ALL. NO CURE FOR THE 46,000 WOMEN WHO WILL DIE OF THIS DISEASE THIS YEAR. NO CURE FOR THE 17 TO 20% WHO WILL BE BETWEEN THE AGE OF 40 AND 49. WHILE RESEARCH IS CONTINUING TO FIND A CURE, THE FEDERAL GOVERNMENT MUST CONTINUE TO ENCOURAGE EARLY DETECTION OF BREAST CANCER. AT THIS TIME, MAMMOGRAPHY IS THE BEST WAY TO DETECT THIS DISEASE.

MR. CHAIRMAN, I AM NOT A SCIENTIST, BUT I AM A WOMAN IN A POSITION TO DO SOMETHING FOR OTHERS IN OUR NATION. I HOPE YOU WILL JOIN ME IN ASKING THE NATIONAL CANCER INSTITUTE TO CONTINUE RESEARCH ON MAMMOGRAPHY TESTING FOR YOUNGER WOMEN. PENDING RESULTS OF SUCH RESEARCH, I IMPLORE NCI TO REINSTATE GUIDELINES WHICH RECOMMEND THAT WOMEN OBTAIN A MAMMOGRAM AT AGE 40. IT COULD MEAN MANY LIVES.

THANK YOU, MR. CHAIRMAN, FOR THIS OPPORTUNITY TO ADDRESS YOUR SUBCOMMITTEE.

NATHANIEL I. BERLIN
19355 TURNBERRY WAY
NORTH MIAMI BEACH, FLORIDA 33180
305-937-1152

March 5, 1994

Miss Allegra Pacheco
Sub-Committee on Human Resources and Inter-Governmental Relations
U.S. House of Representatives
Rayburn Building Room B372
Washington,D.C. 20515

Dear Miss Pacheco

First I want to tell you how much I enjoyed talking to you about breast cancer screening, it was indeed a great pleasure.

I did attend the workshop meeting and now I have read the Fletcher editorial in the Annals of Internal Medicine which I was unaware of until you mentioned it to me. I have read the three articles in the October 20, 1993 issue of the Journal of the National Cancer Institute.

I can best summarize at the outset that at the conclusion of the workshop I came to the conclusion that the workshop was biased and that their conclusions were a forgone conclusion. I communicated that conclusion to some of my colleagues at NCI and I offered to write an editorial for the JNCI. That offer was not accepted. Incidentally that would have been the third editorial I would have written on the subject of breast cancer screening. The second was in the Journal of the American Medical Association, vol 245, 1060, 1981 and the first was in Preventive Medicine vol 8 , pages 573-589, 1979. I am sending you a copy of each.

Despite the stated purposes the organizers were not willing to consider any data that was not derived from a randomized controlled clinical trial although among the stated purposes was "assess the current state of knowledge" It would have been interesting and fascinating to compare the results of the controlled randomized trial with the data published in the JNCI, vol 80,pages 1540-1547,1988

indeed that data derived from the Breast Cancer Detection Demonstration Projects and analyzed by Morrison, Brisson and Khalid and particularly Figure 1 of their paper and the numerical data in their summary agree very well with the data developed at the workshop from the randomized controlled trials.

After reading the Fletcher editorial in the Annals of Internal Medicine and the Sickles and Kopans editorial and the Chalmers editorial in the JNCI I find it difficult to accept the narrow focus of the workshop and even more difficult to brush aside the criticisms of the Canadian studies, they are substantial and the burden of proof is on the Canadians to prove that the admittedly poor initial mammography was not sufficient to invalidate the conclusions.

To be honest randomized trial are the best way to answer some questions, but not the only way. They have their place.

Further if some want to question whether I am impartial, my record is clear, there are the two editorials and if some want to question further I was the NCI official responsible for the Breast Cancer Detection Demonstration Projects from their inception until I left the NCI in 1975.

Last I would like to think that NIH is the National Institutes of Health "research" and not the National Institutes of of Health "care" and that its mission is to develop new knowledge and not to make health care policy.

Yours truly,

Nathaniel I. Berlin

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editorial

Breast Cancer Screening: The Case for Screening Women Younger Than 50 Years

The mortality from breast cancer is almost unchanged, as a result of a constant high incidence and little change in the prospects for cure for the women with breast cancer. The increased use of mammography and adjuvant chemotherapy will probably result in some decrease in the mortality, but it will be some years before this can be observed.

In any consideration of breast cancer today, there are several facts that should be emphasized: approximately one third of the women with breast cancer diagnosed are younger than 50 years; there is a real fear in all women about the loss of the breast; drugs and hormonal therapy as used today are not curative of diagnosed metastatic disease though they may prolong survival; the Halsted radical mastectomy is rapidly being replaced by the modified radical mastectomy; and the quadrantectomy (lumpectomy, limited resection, or tylectomy) has not yet been shown to be the equivalent of the modified radical mastectomy, even though it is not difficult to predict that it will be—at least with respect to mortality.

Given these considerations, what can physicians do today to reduce breast cancer mortality? The one thing that has been shown to be effective is to search (screen) for breast cancer by both a physical examination and x-ray film of the breast. This has been shown to be effective in a carefully designed, randomized controlled clinical trial carried out by the Health Insurance Plan of Greater New York (HIP study).[1]

When the findings of the HIP study became known, the American Cancer Society made a substantial financial commitment to the creation of breast cancer detection demonstration projects and enlisted in this effort the National Cancer Institute. Together these two organizations funded the development of 27 breast cancer detection demonstration projects.

The article by Bland et al in this issue of THE JOURNAL (p 1037) is a report from one of the first three units to be approved and funded and, in particular, reports and calls attention to their findings in the women screened who were younger than 50 years. There seems to be little or no question that women older than 50 years should be screened by physical examination and mammography, but the absence of a demonstrated reduction in mortality in the younger women (younger than 50 years) in the HIP study has led to considerable discussion in the news media and the profession centering largely around the hazard of irradiation to the breast.

Where are we today? First, we know more about the carcinogenic potential of irradiation to the breast than when these projects were initiated, and, in particular, we have learned that the hazard is age dependent, with a peak effect before age 20 years; that there are few data concerning the hazard in women 40 years or older; and that the data show no increase in breast cancer in women who underwent fluoroscopy after having had a child.[2,3] Second, the x-ray dose to the breast to produce a satisfactory mammogram can be and has been substantially reduced. This reduction in x-ray dose is such that the benefit-risk ratio can become extremely large.

What is the benefit today of screening for breast cancer in women younger than 50 years? If benefit is measured by a reduction in mortality, this question cannot be answered. If benefit is measured by the ability to detect cancer in women younger than 50 years in substantial numbers and if these cancers are at a more favorable stage—that is, smaller and with fewer having axillary node metastases—then the data presented by Bland and colleagues show a distinct and substantial benefit. In fact, if these criteria are used, the benefit is equivalent to that seen in the women older than 50 years and that benefit in the HIP study was substantial.

Until a true prevention is achieved or an effective treatment for metastatic breast cancer is developed, the best we have to offer today is "early" diagnosis by searching for breast cancer, and if the limited resection that preserves the architecture of the breast proves to be equivalent to the modified radical mastectomy, we offer the prospect of saving the breast for those women with tumors sufficiently small to permit a limited resection. If this line of reasoning is accepted, the scientific issue today is not whether women aged 40 to 50 years should be screened, but is how frequently the examination should be done.

Demonstration projects should demonstrate, and Bland et al have done so. They were not asked to do more. Regular examination of the breast should become a part of the regular practice of physicians providing care to the women older than 40 years, and this should include a physical examination, an x-ray film of the breast, and instruction in breast self-examination.

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OPENING STATEMENT BY CONGRESSMAN BERNARD SANDERS
MAMMOGRAPHY GUIDELINES HEARING
MARCH 8, 1994 / GOVERNMENT OPERATIONS

I WANT TO THANK CHAIRMAN TOWNS FOR HOLDING THIS HEARING ON MAMMOGRAPHY -- AN ISSUE IS OF VITAL IMPORTANCE TO MILLIONS OF AMERICAN WOMEN. I WANT TO WELCOME MY COLLEAGUES WHO WILL BEGIN TODAY'S TESTIMONY AND SAY THAT IT IS A PLEASURE TO HAVE CONGRESSWOMEN MARY ROSE OAKAR WITH US TODAY. THE CONGRESSWOMAN IS KNOWN AND REMEMBERED FOR HER LEADERSHIP IN MOVING THE ISSUE OF BREAST CANCER TO THE FOREFRONT OF THE NATIONAL AGENDA. SHE JOINED WITH HER FELLOW PANELISTS, PATRICIA SCHROEDER, OLYMPIA SNOWE, AND LOUISE MCINTOSH SLAUGHTER IN SHEDDING LIGHT ON THE FRIGHTENING TOLL THAT CANCER, AND SPECIFICALLY BREAST CANCER HAS TAKEN ON OUR WIVES, SISTERS, MOTHERS AND DAUGHTERS.

ONE IN THREE AMERICANS TODAY WILL BE AFFLICTED WITH CANCER AND ONE IN FOUR WILL DIE OF THAT TERRIBLE DISEASE. IN TERMS OF BREAST CANCER, 182,000 WOMEN THIS YEAR WILL BE DIAGNOSED WITH THIS DISEASE, AND IT IS ESTIMATED THAT 46,000 AMERICAN WOMEN WILL DIE OF BREAST CANCER THIS YEAR. VERY FEW FAMILIES IN OUR COUNTRY DO NOT SUFFER THE LOSS OF ONE OR ANOTHER MEMBER AS A RESULT OF CANCER.

THERE IS AN EPIDEMIC OF BREAST CANCER. THERE HAS BEEN AN ESTIMATED 57 PERCENT INCREASE IN THE INCIDENCE OF BREAST CANCER OVER THE LAST 40 YEARS, AND THE AMERICAN CANCER SOCIETY ESTIMATES THAT BREAST CANCER INCIDENCE RATES HAVE INCREASED ABOUT 3 PERCENT A YEAR SINCE 1980.

CLEARLY, IF WE ARE GOING TO BE EFFECTIVE IN FIGHTING CANCER IN GENERAL, AND BREAST CANCER SPECIFICALLY, WE NEED MORE INFORMATION, OUR RESEARCHERS NEED INFORMATION WHICH WE DO NOT HAVE TODAY. AMAZINGLY, HALF OF THE STATES IN AMERICA TODAY LACK STATEWIDE REGISTRIES THAT COLLECT DATA ON INCIDENCE, STAGE, TREATMENT AND FOLLOW-UP INFORMATION REGARDING CANCER. LAST CONGRESS, I SPONSORED A BILL, "THE NATIONAL CANCER REGISTRIES ACT OF 1992" TO ESTABLISH AND UPGRADE STATEWIDE CANCER REGISTRIES AND WITH THE HELP OF THE CONGRESSWOMEN BEFORE US, ESPECIALLY WITH THE HELP OF REPRESENTATIVE OAKAR, THAT BILL PASSED INTO LAW.

PRINTED ON RECYCLED PAPER

I AM PLEASED TO REPORT THAT MANY STATES, LIKE MY OWN STATE OF VERMONT, HAVE INCLUDED IN THEIR REGISTRIES A SEPARATE REGISTRY FOR MAMMOGRAMS. THESE REGISTRIES SHOULD PROVE USEFUL IN GETTING MORE NECESSARY INFORMATION ABOUT MAMMOGRAPHY SCREENING. AND I SHOULD POINT OUT THAT THANKS TO THE HARD WORK OF REPRESENTATIVE SCHROEDER, MAMMOGRAPHY NOW HAS ESTABLISHED STANDARDS FOR QUALITY AND EFFECTIVENESS.

I BELIEVE IF WE HAD STARTED OUR "WAR ON CANCER" IN THE 1970S BY KEEPING THE VITAL STATISTICS ON CANCER SURVIVORS AND VICTIMS, (WHICH WE ARE FINALLY BEGIN TO KEEP IN ALL OUR STATES), WE WOULD BE A LOT FARTHER ALONG TODAY IN THAT WAR. INFORMATION, ACCURATE INFORMATION IS CRUCIAL IN OUR STRUGGLE TO UNDERSTAND, PREVENT AND CONTROL THIS DISEASE. THAT IS WHY I BELIEVE TODAY'S HEARING IS IMPORTANT.

TODAY'S HEARING IS ABOUT THE INTERNATIONAL CONTROVERSY OVER MAMMOGRAPHY. IT IS A CONTROVERSY, AND I BELIEVE THE JURY IS STILL OUT. THE TRUTH IS THAT DECENT, HONEST PEOPLE DISAGREE OVER WHETHER WOMEN 40-49 SHOULD HAVE A MAMMOGRAM. BUT THAT DISAGREEMENT SHOULD NOT LEAD US TO DENY WOMEN OF THEIR RIGHT TO MAKE A CHOICE, OR DENY THEM THE INSURANCE COVERAGE THAT IS NECESSARY TO HAVE A MAMMOGRAM. AS DR. BRODER HIMSELF HAS SAID, "WHAT I WOULD DO AS AN INDIVIDUAL IS RECOMMEND ANNUAL MAMMOGRAMS."

WE HAVE TO PRESERVE THE DOCTOR--PATIENT RELATIONSHIP IN THIS VERY IMPORTANT DECISION. WE HAVE TO CONTINUE TO RESEARCH THIS SUBJECT UNTIL THE EVIDENCE IS MORE CONCLUSIVE ONE WAY OR THE OTHER. I SUPPORT THAT RESEARCH -- I SUPPORT FURTHER INQUIRY INTO THIS CONTROVERSIAL SUBJECT. BUT IN THE MEANTIME, INSURANCE COVERAGE MUST BE AVAILABLE FOR WOMEN 40-49, SO THEY CAN WORK WITH THEIR DOCTOR TO MAKE A DECISION THAT IS BEST FOR THEM. FOR THE 28,000 WOMEN 40-49 WHO WILL BE DIAGNOSED WITH BREAST CANCER THIS YEAR, THAT CHOICE IS VERY IMPORTANT AND SHOULD NOT BE DENIED.

STATEMENT BY THE HON. PETER T. KING

BEFORE THE

COMMITTEE ON GOVERNMENT OPERATIONS

SUBCOMMITTEE ON HUMAN RESOURCES & INTERGOVERNMENTAL RELATIONS

NATIONAL CANCER INSTITUTE'S REVISION OF ITS

MAMMOGRAPHY GUIDELINES

MARCH 8, 1994

Mr. Chairman, I would like to commend you for holding this important hearing on the National Cancer Institute's decision to revise its mammography guidelines for women between the ages of 40 and 49. This issue is very important to me and to the hundreds of thousands of women on Long Island where the incidence of breast cancer is extremely high.

At a time when public awareness about the life saving potential of mammographies is at an all time high, NCI's new guidelines send women a confusing message. The result is likely to be that women may play a deadly game of Russian roulette and postpone their first mammography until after age 50.

This is quite disturbing in that 25 percent of all new breast cancers this year will occur in women under the age of 50. This translates to approximately 29,000 cases in the 40 to 49 age group.

While no conclusive evidence exists to prove or disprove the

value of screening women in their forties, there is a growing body of evidence that routine screening of women under age 50 can decrease breast cancer mortality in this age group by 13-24 percent. More recent studies including a combined Swedish trial and the American Cancer Society/National Cancer Institute breast cancer detection demonstration project indicate marked reductions in mortality in the 40 to 49 age group.

In November, I joined with 30 of my colleagues in sending a letter to President Clinton urging him to retain the current NCI mammography guidelines until further trials and studies could be completed on the effectiveness of mammographies on women in their forties. Unfortunately, the President, whose own health care reform plan only provides coverage for biannual mammographies for women over age 50, was unable to prevent the NCI's new guidelines from being finalized.

Regardless of the NCI's new guidelines, I believe that we must continue to encourage women to receive mammographies. I look forward to working with you Mr. Chairman, in ensuring that the important role that mammographies play in detecting breast cancer is highlighted during the upcoming debate on health care reform.

Thank you, Mr. Chairman.

The Breast Is Close to the Heart

Years ago, like thousands of second-year medical students before and since, we began mastering the mysteries of physical diagnosis. We learned the secrets of heart sounds—the systolic ejection murmur, the diastolic whiff, the rumble at the apex—and how to palpate, percuss, and auscultate the chest for breath sounds, rales, rhonchi, dullness, and egophony. It was heady stuff. We concentrated on the examination of the chest, perhaps because we were taught by internists (most physical diagnosis courses still are), and internists love examining the heart and lungs. Neither of us has any memory of being taught how to examine the breast.

That same year, 1963, the famous Health Insurance Plan (HIP) randomized trial of breast cancer screening began (1). Eight years later, in the Hypertension Clinic, one of us was aghast to accidentally discover a small dimpling area on the inferolateral side of the right breast in a patient followed for hypertension. The patient was the one in eight or nine North American women unlucky enough to develop breast cancer; like 75% of such women, she was over age 50 when she developed it.

About that time, HIP published the first results demonstrating that breast cancer screening with physical examination and mammography saved lives (2). In the two decades since, at least five major randomized controlled trials, three case-control studies, and one cohort study have been conducted, all finding that screening for breast cancer saves lives in women ages 50 to 74 (the upper age limit studied in any trial). The randomized trials found reductions in mortality ranging from 20% to 39% among women over 50 years of age (3). Rarely has clinical science produced such consistent results, even though it is true that not all studies achieved statistical significance. Every North American expert group issuing guidelines on breast cancer screening recommends routine screening for women 50 years of age and older (3).

In 1992, the question no longer is whether to screen women for breast cancer, but at what age to begin, what screening technique to use, and how better to incorporate the practice into patient care. Two reports of the Canadian National Breast Screening Study published 2 weeks ago (4, 5) bear on the questions of age and type of screening test. A report by Coleman and colleagues in this issue of *Annals* (6) addresses the third question.

The major dispute in breast cancer screening today concerns offering routine mammography to women in their forties; expert groups are split on their recommen-

dations (3). The first of the Canadian studies addresses this question; it is a large-scale, randomized trial involving 50 000 women ages 40 to 49. Results after 7 years of follow-up show that screening women in this age group with annual physical examination and mammography produced no reduction in mortality. The risk for dying of breast cancer was actually higher in the group of women who were screened than in the control group, with a relative risk of 1.36, but the 95% confidence interval was 0.84 to 2.21. Four previous randomized trials, with smaller numbers of women and 7 to 11 years of follow-up, also found no benefit from screening women under 50 years of age with physical examination and mammography or from mammography alone (7-10). Mortality differences ranged from 2% excess mortality in the control group to 29% excess mortality in the screened group, but none of the differences was statistically significant.

The only randomized trial to find a reduction in breast cancer mortality after screening women in their forties is the HIP study. In that study, mortality benefits began appearing after 5 to 8 years of follow-up, and by 18 years, a 25% mortality benefit was found for the screened group of women (1). This finding has been analyzed extensively and has been cited as support for screening women in their forties (11). However, HIP investigators concluded, "The numbers are small and none of the differences is statistically significant, but these observations cast doubt on the ability to conclude from the HIP project that initiation of screening under the age of fifty was efficacious" (1).

The Canadian study (4) has been criticized for the quality of the mammograms performed (12). Poor-quality mammograms and the fact that a quarter of the women in the control group received at least one mammogram during the study might lessen, but would be unlikely to nullify completely, any mortality benefit (let alone to cause screened women to fare worse). Furthermore, even the Two County Study in Sweden, directed by famed mammographer Lazlo Tabar, found no mortality advantage of screening women under age 50 after 11 years of follow-up (7); the mortality curves in the two groups are almost superimposed on one another, with slightly higher rates among the screened group of women.

Groups recommending routine breast cancer screening in women under age 50 should review their recommendations. Breast cancer at any age is a devastating disease, but the fact that screening is effective in older women is not a valid argument to screen younger ones. The biology of breast cancer varies among age groups in a variety of ways, such as hormonal receptor status; there is some evidence that breast cancers in younger women are more aggressive, with shorter lead times for screening (2, 7). Normal breast tissue also varies with the age of the woman, with less fatty tissue in the breasts of younger women making detecting breast cancer by physical examination and mammography more difficult. These factors could lead to different degrees of screening effectiveness in different age groups.

Regardless of the reasons for the findings in all these studies, the simple fact is that a universal hope has not stood up to scientific scrutiny. (A similar situation has happened before, with the use of routine chest radiographs for lung cancer screening.) Medical scientists and physicians do not do modern women a service by promulgating a screening practice that medical science has not been able to substantiate after so many tries. We serve them far better by continuing the search for a practice that does work.

The second Canadian study (5) assesses the effect of mammography over that of a careful clinical breast examination alone among women in their fifties. The results are likely to be just as controversial as the results of the first study. For the first time, a randomized trial has examined the individual effects of the two screening modalities, finding surprisingly that over the first 7 years of follow-up, mammography does not confer additional mortality benefit after a careful clinical breast examination (relative risk, 0.97; 95% CI, 0.62 to 1.52). Considerably more node-negative breast cancers were detected by mammography than by physical examination, which is similar to results of previous studies. The authors indicate that longer follow-up may be necessary to detect any possible mortality benefit.

Again, critics have blamed the results of the study on poor-quality mammograms. Few have considered that the results might be due to high-quality physical examinations. In the Canadian study all examiners (mostly nurses) were carefully trained with a standardized technique (13).

Can fingers be taught to be as good as mammography? Researchers at the University of Florida have demonstrated that the human finger can detect simulated breast cancers as small as 3 mm in silicone models (14-16). Studies with medical residents and nurses (17), women patients (18), and medical students (Pilgrim C. Personal communication) have all shown that lump detection ability in these simulated circumstances can be improved with training. Many physicians would like to improve their detection skills; in one study of 80 physicians from 43 medical schools, 84% felt the need (19). Like us, many could recall no training in how to do the clinical breast examination.

We suspect few physicians would be comfortable relying solely on a clinical breast examination for breast cancer screening. Given the relatively early results from a single study and the likely state of most physicians' skills, we agree. Nevertheless, it is time to reconsider this part of the physical examination, to better teach ourselves and our students. More must be learned about how to perform an adequate breast examination.

Perhaps the biggest problem in breast cancer screening today is not the scientific disagreement about the evidence but the poor performance of breast cancer screening where agreement exists. In this issue, Coleman and colleagues found that although mammography use among white women ages 65 to 74 increased from 1987 to 1991, 41% to 65% of the women in this age group surveyed in five communities across the United States during 1991 had not had a mammogram in the previous year (6). Performance of clinical breast examinations, although much more common, had actually declined. Other recent surveys, including a national one conducted in 1992 (20) indicate that at least a quarter of women over age 50 have never had a mammogram.

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Why should internists take note of such statistics? The answer is simple. These are our patients. Internists are the major source of medical care for women over age 50 in this country. The failure to screen these women for breast cancer is partly our failure. The work by Coleman and colleagues is the latest to show, once again, that most women who are advised by their physicians to get mammograms do so and that most women who have not been screened do not know they need screening and cannot recall their physicians discussing mammography with them. Almost every internist, regardless of subspecialty, makes sure the patient's blood pressure is taken routinely. These efforts have helped reverse the epidemic of cardiovascular disease deaths in this country. We can make similar strides in breast cancer deaths—if we only remember the breast is close to the heart.

Suzanne W. Fletcher, MD *Robert H. Fletcher, MD*
Editors

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Annals Editors Speak Out on Breast Cancer:
- Groups Should Review Recommendations for Screening Women Under 50
- Internists Must Do More About Breast Cancer in Older Women

Suzanne W. Fletcher, MD, and Robert F. Fletcher, MD, editors of Annals of Internal Medicine, call for organizations recommending routine breast cancer screening in women under age 50 to review their recommendations. Their editorial appears in the Dec. 1, 1992, issue of Annals. Many studies have found that breast cancer screening saves lives in women aged 50 to 74, they say, but other studies, including a recent Canadian study, have found no mortality advantage of screening women under age 50. "The fact that screening is effective in older women is not a valid argument to screen younger ones," they say.

Meanwhile, says Dr. Suzanne Fletcher, "We should act on what we know for sure--that routine screening is effective in women over age 50." The NCI/NIH study in this issue of Annals shows that many of these women don't get mammograms and that they don't know mammography screening is important and effective, she said.

The Fletchers urge internists to perform clinical breast exams properly and to recommend mammography for their women patients over age 50. Internists are the major source of medical care for women over age 50 in the U.S., they say. Almost every internist "makes sure the patient's blood pressure is taken routinely--efforts which have helped reverse the epidemic of cardiovascular disease deaths in this country," they say. "We can make similar strides in breast cancer deaths."

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NOTE: Suzanne W. Fletcher, MD, is available for interview.

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